

Appendix 16: Monitoring Potential Exposure

I. General

A. Action Level

1. The “action level” is defined as an airborne concentration of the New Chemical Substance, calculated as an 8-hour time-weighted average, equal to one half the NCEL
TWA specified in Appendix 10 Section IIIB 2 ai.
2. For non-8-hour work shifts, the action level is equal to one half the NCELn. (The NCELn is described in Appendix 10 Section III B 2 aii.)
3. The Company may exceed the action level without penalty. The purpose of the action level is solely to determine the requisite monitoring frequency.

B. Representative Exposure Groups

1. Whenever exposure monitoring is required by this New Chemical Exposure Limit section, the Company must take representative samples of what the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of the New Chemical Substance would be if respirators were not worn.
2. The Company must do so by sampling the breathing zone air of at least one person that represents, and does not underestimate, the potential exposure of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area (hereinafter identified as an “exposure group”) where inhalation exposure to the New Chemical Substance is reasonably likely to occur.
3. The exposure of each person need not be itself directly sampled if that exposure is represented by sampling the exposure of another person in the same exposure group.

C. Good Laboratory Practice Standards

Determinations of potential inhalation exposure must be made according to TSCA Good Laboratory Practice Standards at 40 C.F.R. part 792 and the sampling and analytical method developed pursuant to Appendix XV Performance Criteria for Sampling and Analytical Method. (Certain provisions of the TSCA GLPS applicable to toxicity testing in laboratory animals, such as 40 C.F.R. 792.43 ("Test system care facilities"), 792.45 ("Test system supply facilities") and 792.90 ("Animal and other test system care"), are clearly inapplicable to the NCEL requirements.) However, compliance with TSCA GLPS is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA IHLAP; or (B) another comparable program approved in advance in writing by EPA.

D. Full Shift Exposure Samples

Representative 8-hour TWA airborne concentrations must be determined on the basis of samples representing the full shift exposure for each exposure group.

E. STEL Samples

Determinations of compliance with the STEL must be made from 15 minute breathing zone samples measured at operations where there is reason to believe that the maximum short-term exposures will occur, such as during, but not limited to, the following operations: _____. **[Note to Program Managers: Delete this paragraph if there is no STEL.]**

II. Initial Monitoring

Before the Company may deviate from the respirator requirements in Appendix 10 Section III A, the Company must conduct initial exposure monitoring to accurately determine the airborne concentration of the New Chemical Substance for each exposure group in which persons are reasonably likely to be exposed to the New Chemical Substance.

III. Periodic Monitoring

- A. If any representative samples taken during the initial exposure monitoring reveal an airborne concentration at or above the action level but at or below the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 6 months. If the New Chemical Substance is not manufactured, processed, or used at all during a given 6-month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the New Chemical Substance is resumed. However, cessation of manufacturing, processing and use of the New Chemical Substance for less than the 6-month period does not constitute grounds for postponement of the 6-month deadline to conduct exposure monitoring.
- B. If any representative samples taken during the initial exposure monitoring reveal an airborne concentration above the TWA, the Company must repeat the exposure monitoring for that exposure group at least every 3 months. If the New Chemical Substance is not manufactured, processed, or used at all during a given 3-month calendar period, the Company is not required to conduct exposure monitoring until manufacture, processing, or use of the New Chemical Substance is resumed. Cessation of manufacturing, processing, and use of the New Chemical Substance for less than the 3-month period, however, does not constitute grounds for postponement of the 3-month deadline to conduct exposure monitoring.
- C. The Company may alter the exposure monitoring schedule from every 3 months to every 6 months for any exposure group for whom two consecutive measurements taken at least 7 days apart indicate that the potential exposure has decreased to the TWA or below, but is at or above the action level. Where the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

IV. Termination of Monitoring

- A. If representative samples taken during the initial exposure monitoring reveal an airborne concentration below the action level, the Company may discontinue monitoring for that exposure group, except when additional exposure monitoring is required by Additional Monitoring Section 5 of this Appendix.
- B. If representative samples taken during the periodic monitoring reveal that an airborne concentration, as indicated by at least 2 consecutive measurements taken at least 7 days apart, are below the action level, the Company may discontinue the monitoring for that exposure group, except when additional monitoring is required by Additional Monitoring Section 5 of this Appendix. Where the New Chemical Substance is manufactured, processed, or used in batches of duration less than 7 days, the 2 consecutive measurements may be taken at least 24 hours apart, provided that the measurements accurately reflect the highest peak exposures and variability in exposure.

V. Additional Monitoring

- A. For a previously monitored exposure group, the Company must, within 7 days of any of the events listed below conduct the initial exposure monitoring followed by any periodic exposure monitoring required by Section II and Section III of this Appendix:
 - 1. change in the production volume, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the New Chemical Substance;
 - 2. spills, leaks, ruptures or other breakdowns occur that may reasonably cause new or additional exposures to the New Chemical Substance; and
 - 3. whenever else the Company has any reason to suspect a change that may reasonably result in new or additional exposures to the New Chemical Substance.
- B. In no event is the additional exposure monitoring requirement in Section V of this Appendix intended to delay implementation of any necessary cleanup or other remedial action. During any cleanup or remedial operations that may occur before commencing

additional exposure monitoring, the Company must ensure that potentially exposed persons use at least the respiratory protection specified in Appendix X Section III a for the measured airborne concentration, or more protective respiratory equipment deemed appropriate by the best professional judgment of a qualified expert.

VI. Notification of Monitoring Results

- A. Within 15 working days after receipt of the results of any exposure monitoring required by this Order, the Company must notify each person whose exposure is represented by that monitoring. The notice must identify the NCEL, the exposure monitoring results, and any corresponding respiratory protection required by Appendix 10 Section III a. Affected persons must be notified in writing either individually or by posting the information in an appropriate and accessible location.
- B. Whenever the NCEL is exceeded, the written notification required by the preceding paragraph must describe the action being taken by the Company to reduce inhalation exposure to or below the NCEL, or must refer to a document available to the person which states the actions to be taken to reduce exposure.

VII. Exemption based on Objective Data

- A. Where the Company has documented and reliable objective data demonstrating that, even under worst-case conditions, employee exposure to the New Chemical Substance will not exceed the action level (Section I A of this Appendix) under the expected handling procedures and conditions for a specific "exposure group" (defined in Section I B of this Appendix), then that exposure group is exempt from the requirements of the New Chemical Exposure Limit section (Appendix 10 Section III) except Section V Additional Monitoring of this Appendix, NCEL Recordkeeping Requirements in Appendix 18 and the respirator requirements in the Protection in the Workplace Appendix 10 Section III.
- B. Any such objective data must accurately characterize actual employee exposures to the New Chemical Substance and must be obtained under conditions closely resembling the

types of materials, processes, control methods, work practices, and environmental conditions in the Company's current workplace operations with the New Chemical Substance. Examples of objective data that may be used to demonstrate that employee exposure will not exceed the action level, even under worst case conditions, include information on the physical and chemical properties of the New Chemical Substance, industry-wide studies, and/or laboratory test results.

Appendix 17: Statistical Analysis of NCEs Analytical Method Verification Results

This Attachment describes the statistical technique (with examples) for comparing the analytical results obtained by two laboratories pursuant to Appendix XV of this Order.

STATISTICAL TECHNIQUE

To obtain two-sample t test with unequal variances, perform the following operations:

- Compute means of the data measured by two laboratories.
- Compute mean squares

$$S_i^2 = \sum (X_{ij} - \bar{X}_i)^2 / (n_i - 1), i=1, 2$$

- Form the ratio

$$T = (\bar{X}_1 - \bar{X}_2) / (W_1 + W_2)^{1/2}$$

- Compute degrees of freedom

$$f = (W_1 + W_2)^2 / [W_1^2 / (n_1 - 1) + W_2^2 / (n_2 - 1)]$$

where,

$$W_i = S_i^2 / n_i, i = 1, 2$$

\bar{X}_1 = Average of the results from the company laboratory

\bar{X}_2 = Average of the results from the independent laboratory

n_1 = Number of samples analyzed by the company laboratory

n_2 = Number of samples analyzed by the independent laboratory.

Then compare the absolute value of T to the 97.5 percentile point of a t distribution with f degrees of freedom. If the absolute value exceeds the 97.5 percentile point, the results

measured by two laboratories are significantly different at 95% level. Otherwise, they are not significantly different. In general, f may not be an integer. Use interpolation to obtain the 97.5 percentile point of a t distribution with f degrees of freedom.

EXAMPLES -- The following examples (based on simulated data) illustrate the method:

Example 1

Data Set 1	Data Set 2
80.56	97.11
100.01	102.13
86.04	99.83
52.61	97.83
84.85	105.44
95.75	100.04

$$X_1 = 83.30 \quad n_1 = 6 \quad X_2 = 100.40 \quad n_2 = 6$$

$$S_1^2 = 278.72 \quad W_1 = 46.25 \quad S_2^2 = 9.26 \quad W_2 = 1.54$$

$$\text{Absolute value of } T = 2.467 \quad f = 5.33$$

The t table shows that the 97.5 percentile point is 2.571 and 2.447 for 5 and 6 degrees of freedom, respectively. For 5.33 degrees of freedom, the 97.5 percentile point will be approximately 2.530 which is greater than the absolute value of T , 2.467. Hence, the means of two data sets are not significantly different at the 5% level.

However, if this problem had been treated as an ordinary two-sample t test, the means would be significantly different at the 5% level because the absolute of T is greater than 2.228, the 97.5 percentile point for the t distribution with 10 degrees of freedom.

Example 2

Data Set 1	Data Set 2
82.87	108.05
101.85	96.51
87.44	100.04
99.68	104.33
101.15	110.32
99.21	107.00

$$\begin{aligned} X_1 &= 95.37 & n_1 &= 6 & X_2 &= 104.37 & n_2 &= 6 \\ S_1^2 &= 65.59 & W_1 &= 10.93 & S_2^2 &= 27.25 & W^2 &= 4.54 \end{aligned}$$

$$\text{Absolute value of } T = 2.290 \quad f = 8.54$$

The t table shows that for 8 and 9 degrees of freedom the 97.5 percentile point is 2.306 and 2.262, respectively. For 8.54 degrees of freedom the 97.5 percentile point will be approximately 2.282 which is less than the absolute value of T, 2.290. Hence, the means of two data sets are significantly different at the 5% level.

Appendix 18: NCEL Recordkeeping

Whenever the Company elects to comply with the New Chemical Exposure Limit section rather than the respirator requirements in the Protection in the Workplace section of this Order, the Company must maintain the following records until 30 years after the date they are created, and must make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

1. Records documenting compliance with the analytical method verification requirements of Appendix 15, including copies of the signed certification statement and the verification results obtained by both laboratories;
2. Records documenting either compliance with the Good Laboratory Practice Standards at 40 C.F.R. part 792, or use of a laboratory accredited by the AIHA or another comparable program approved in advance in writing by EPA. Where the Company elects to not comply with TSCA GLPS, such records must include the written accreditation from the AIHA or the written approval from EPA.
3. Records documenting all exposure monitoring dates, duration, and results of each sample taken;
4. Records documenting the name, address, work shift, job classification, and work area of the person monitored and of all other persons whose exposures the monitoring is intended to represent;
5. Any conditions that might have affected the monitoring results;
6. Notification of exposure monitoring results required by Appendix 16 ;
7. Records documenting any changes in the production, process, control equipment, personnel or work practices that may reasonably cause new or additional exposures to the New Chemical Substance;
8. Records documenting any spills, leaks, ruptures or other breakdowns that may cause new or additional exposure;
9. The type of respiratory protective devices worn by the monitored person, if any;

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10. Records documenting any actions taken to mitigate exposures to the New Chemical Substance; and
11. Records documenting reliance on the objective data exemption in Appendix 16, including:
 - (A) the source of the data,
 - (B) protocols and results of any relevant testing or analysis,
 - (C) a description of the operation exempted and how the data demonstrate that employee exposures will not exceed the action level,
 - (D) other data relevant to the operations, materials and employee exposures covered by the exemption.

Appendix 19: NCEs Respirator Tables

[EMBED Excel.Sheet.12]

Particulate Respirator Table

Measured Concentration of PMN Substance	Required Respiratory Protection
\leq NCEL	No respiratory protection is required
$\leq 10 \times$ NCEL	<p>(I) Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters.</p> <p>(II) Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. [Note: for filtering facepieces, an APF of 10 can only be achieved if the respirator is qualitatively or quantitatively fit tested on individual workers].</p> <p>(III) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. A full facepiece air-purifying respirator, although it has a higher APF of 50, is required to provide full face protection because the PMN substance presents significant exposure concern for mucous membranes, eyes, or skin.</p> <p>(IV) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [</p> <p>(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask.</p>
$\leq 25 \times$ NCEL	<p>(I) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and HEPA filters.</p> <p>(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters.</p> <p>(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.</p> <p>(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.</p>
$\leq 50 \times$ NCEL	<p>(I) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s).</p> <p>(II) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and equipped with HEPA filters.</p> <p>(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a half-mask.</p> <p>(IV) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.</p> <p>(V) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).</p>
$\leq 1000 \times$ NCEL	<p>(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.</p> <p>(I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters.</p>

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

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(II) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet* and N100 (if oil aerosols absent), R100, or P100 filters with evidence demonstrating protection level of 1,000 or greater.

(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater.

(V) Any NIOSH-certified supplied-air respirator equipped with a full facepiece.

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Any NIOSH-certified pressure-demand or other positive pressure mode (max. 10,000 x (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

> 1000 x NCEL
(max 10,000 x NCEL)

[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]

[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]

Gas/Vapor

If Data on Cartridge Service Life Testing has been Reviewed and Approved

Measured Concentration of PMN Substance

\leq NCEL

$\leq 10 \times$ NCEL

$\leq 25 \times$ NCEL

$\leq 50 \times$ NCEL

Required Respiratory Protection

No respiratory protection is required

(I) Any NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(II) Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask.

(I) Any NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.

(I) Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific).

(II) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific).

If No Cartridge Service Life Testing has been Conducted

Measured Concentration of PMN Substance

\leq NCEL

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

$\leq 10 \times$ NCEL

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

$\leq 25 \times$ NCEL

$\leq 50 \times$ NCEL

Required Respiratory Protection

No respiratory protection is required

(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

Note to Program Manager: If a concern exists for eye/skin

(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece).

exposure from the chemical, delete the half facepiece respirator

(III) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

(I) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

Note to Program Manager: If a concern exists for eye/skin

(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

exposure from the chemical, delete the half facepiece respirator

$\leq 1000 \times \text{NCEL}$

$> 1000 \times \text{NCEL}$
(max 10,000 x NCEL)

(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

(V) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood, helmet, or a full facepiece.

(I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.

(II) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges with evidence demonstrating protection level of 1,000 or greater. *

(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. *

VI) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

$\leq 1000 \times \text{NCEL}$

[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]

[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]

$> 1000 \times \text{NCEL}$
(max 10,000 \times NCEL)

(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

(IV) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood, helmet, or a full facepiece.

(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. *

[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]

(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Combination

If Data on Cartridge Service Life Testing has been Reviewed and Approved

Measured Concentration of PMN Substance

≤ NCEL

≤ 10 x NCEL

≤ 25 x NCEL

≤ 50 x NCEL

Required Respiratory Protection

No respiratory protection is required

(I) Any NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

(II) Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask.

(I) Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.

(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.

(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.

(I) Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters.

If No Cartridge Service Life Testing has been Conducted

Measured Concentration of PMN Substance

\leq NCEL

$\leq 10 \times$ NCEL

$\leq 25 \times$ NCEL

$\leq 50 \times$ NCEL

Required Respiratory Protection

No respiratory protection is required

(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece).

(III) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask.

(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.

(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

(I) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator

$\leq 1000 \times \text{NCEL}$

$> 1000 \times \text{NCEL}$
(max 10,000 x NCEL)

(II)Any NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half or full facepiece) equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

(III)Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

(IV)Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

(V)Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

(VI)Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

(I)Any NIOSH-certified powered air purifying full facepiece respirator equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.

(II)Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters with evidence demonstrating protection level of 1,000 or greater. *

Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator

(III)Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.

(IV)Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet *with evidence demonstrating protection level of 1,000 or greater.* *

Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator

(V)Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

$\leq 1000 \times \text{NCEL}$

$> 1000 \times \text{NCEL}$
(max 10,000 x NCEL)

(II)Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

(III)Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece).

(IV)Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

(I)Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].

(II)Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet *with evidence demonstrating protection level of 1,000 or greater.* *

(III)Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

Any NIOSH-certified pressure-demand or other positive pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator

Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator

cepiece. [provides eye/face protectior

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 7/15/2019 2:19:51 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Letter
Attachments: Letter to AA Dunn re. polysaccharide (Sanitized Version) (00270863xAA4DC).pdf

Good Morning Alex:

We wanted to give you a heads-up on this case. After reviewing the study, RAD and Todd recommended low hazard and to rescind the SNUR. We understand that Dr. Henry has disagreed and has sent the hazard assessment back to RAD. We do not yet have the updated hazard and health assessments to know the basis of the disagreement. .

Rich has requested a status update from the program manager, but the assessment is not yet forthcoming. We may need to elevate this case given Jeff's absence.

Thanks,

Lynn

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Sanitized Version

May 21, 2019

Via Hand Delivery

The Honorable Alexandra Dapolito Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave., N.W.
MC 7101M
Washington, D.C. 20460

Re: Polysaccharide Premanufacture Notice

Dear Assistant Administrator Dunn:

We are writing to express our concern over the way that the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) has addressed a premanufacture notice (PMN) submitted by [REDACTED] in 2016.

[REDACTED] submitted a PMN in 2016 for a polysaccharide derived enzymatically from simple sugars; the PMN was assigned Case Number P-16-0581. The polysaccharide is intended to be used as an additive in various plastic, paper, or other industrial applications to provide state-of-the-art material performance while using a substance that is inherently renewable and biodegradable. The biodegradability is especially important when used as an additive in these and other applications. Rapidly growing interest from consumers, brand owners, non-governmental organizations (NGO), and governmental organizations to address the growing global plastic pollution crisis and sustainable management of single use products is accelerating demand for new material solutions. This [REDACTED] polysaccharide is the basis of a platform that will add new innovative options to address this crisis. Swift action by EPA will enable first commercial applications by [REDACTED] and will accelerate replacement of non-biodegradable plastics that are contributing to the global plastic pollution crisis.

EPA's review focused on concerns for lung effects for workers. OPPT did not predict any aquatic toxicity, nor did it identify any hazards other than the potential for lung overload for poorly soluble particles (PSP).¹ As OPPT is aware, lung overload occurs when

¹ Structure Activity Team (SAT) Report for P-16-0581 (Jan. 6, 2018); TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-16-0581 (October 9, 2018), available

The Honorable Alexandra Dapolito Dunn

May 21, 2019

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exposure to PSPs exceeds the lung's ability to clear the particles. In response to EPA's concerns and the protracted review process, about one and a half years after the original submission, [REDACTED] amended the PMN to remove a grinding step in which large, non-respirable particles are ground down to a nominal size of 17-20 microns, with a distribution that has slightly more than five percent of particles at less than ten microns. Particles of this size are desired for use by downstream customers in the large majority of their polymer, composite, and fiber compounding applications, but, the size of these particles makes them respirable (able to penetrate the deep lung). For this reason, action was taken by [REDACTED] to first gain EPA approval to manufacture and market the un-ground polysaccharide for those limited opportunities for which a larger particle size will suffice to bring the desired technical effects.

[REDACTED] then continued to negotiate with EPA to identify a path for regulatory approval for production of the ground polysaccharide, as the ground material represents the greatest opportunity for this innovation to help address the global plastics pollution crisis. Despite the fact that this severely curtails the commercial potential for the product, [REDACTED] agreed to limit production to a larger, non-respirable size. Here, EPA no longer had a concern, but grinding was still reasonably foreseeable, so OPPT proposed a "not likely based on SNUR," that is, to propose a Significant New Use Rule (SNUR) prohibiting grinding below ten microns and making a "not likely to present unreasonable risk" determination. While EPA was working out the details on issuing the SNUR, [REDACTED] worked with OPPT's Risk Assessment Division (RAD) scientists to find an alternative to EPA's proposed 90-day inhalation testing in rats. [REDACTED] and RAD agreed that [REDACTED] would perform an *in vitro* simulated lung fluid test to determine with a rigorous scientific approach if the product was, in fact, poorly soluble. Since [REDACTED] concluded the testing after the comment period on the proposed SNUR closed, but before the final SNUR was published, it contacted staff in the Chemical Control Division (CCD) to request that OPPT delay promulgating the SNUR in final until RAD had reviewed the test results. The thinking was that if RAD concluded, as [REDACTED] had, that the results demonstrated that the polysaccharide is soluble in simulated lung fluid, EPA's sole concern would be addressed, the substance would then be considered low hazard, and no regulatory action would be necessary. In that case, publishing the SNUR in final, only to rescind it when the study review was complete, would be a significant waste of OPPT resources and would further delay [REDACTED]'s expansion of its commercial opportunities and the adoption of this innovative solution to help address the global plastics pollution crisis.

at https://www.epa.gov/sites/production/files/2018-10/documents/p-16-0581_determination_non-cbi_final.pdf.

The Honorable Alexandra Dapolito Dunn
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Page 3

██████████ and its representatives from Bergeson & Campbell, P.C. (B&C[®]) spoke with or e-mailed the case manager, the team lead in charge of the SNUR, the Branch Chief of the New Chemicals Management Branch, and finally Dr. Tala Henry, Acting Deputy Director of OPPT. Dr. Henry stated that even if RAD's assessment demonstrated biosolubility, RAD could not conclude that the substance was low hazard without *in vivo* testing, despite the fact that biosolubility testing is: (1) identified as the first tier of testing in the Poorly Soluble Particulate Category, a category to which ██████████ has now demonstrated that the polysaccharide does not fall; and (2) RAD agreeing that the *in vitro* method proposed by ██████████ would inform RAD's view of the hazard. Despite ██████████'s best efforts, the final SNUR was promulgated prior to RAD completing its review of the biosolubility study. Furthermore, ██████████ found out about the promulgation when the SNUR was made public. Despite our close and repeated contact with OPPT, surprisingly management neglected to inform ██████████ of OPPT's decision prior to promulgation.

Since the SNUR was promulgated, ██████████ convened a conference call with OPPT toxicologists and risk assessors to discuss RAD's view of the study. That call revealed that, although indications are that RAD agrees that the *in vitro* study did demonstrate solubility in simulated lung fluid, it is not clear what the outcome will be out of the study review. ██████████ is still waiting for RAD's updated health assessment. Based on our limited understanding, OPPT seems to be proposing to modify, rather than rescind, the SNUR, despite the study having demonstrated that the substance is not a PSP.

██████████ has been exceedingly patient and has negotiated with OPPT in good faith. OPPT, on the other hand, seems to be insistent upon regulating the substance, regardless of data that support that the substance does not present unreasonable risk under the reasonably foreseeable conditions of use simply because the substance does not exhibit the properties that EPA predicted (*i.e.*, that it is a PSP).

██████████ respectfully requests that OPPT provide clarity on:

1. RAD's view of the biosolubility study. If RAD disagrees with ██████████'s interpretation of the study, the basis for that disagreement;
2. Why RAD would agree to consider *in vitro* testing in lieu of *in vivo* testing if the *in vitro* testing was never going to be sufficient to demonstrate low hazard. If RAD needed both *in vitro* and *in vivo* testing to conclude that the

The Honorable Alexandra Dapolito Dunn
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Page 4

substance is low hazard, RAD should have so stated when discussing the *in vitro* testing.

3. If RAD now views the product as biosoluble, why OPPT is proposing modifying, rather than rescinding, the SNUR. If the substance is indeed biosoluble then there are no hazards that would require EPA to protect against with a SNUR.
4. OPPT's proposed path to remedy its hasty promulgation of a SNUR when there were data that might demonstrate that the SNUR was not necessary that was days or weeks away from being reviewed; and
5. Why OPPT did not inform [REDACTED] of its decision to proceed with publishing the SNUR prior to doing so (except to deny [REDACTED] the opportunity to further advocate for its position).

Finally, [REDACTED] respectfully requests a meeting with you and any staff and management from OPPT or the Office of Chemical Safety and Pollution Prevention (OCSPP) that you feel should attend.

Sincerely,



Richard E. Engler, Ph.D.
Director of Chemistry

cc: Lynn L. Bergeson, Esquire (via e-mail)

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 6/20/2020 5:03:13 PM
To: Fischer, David [Fischer.David@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; 'Michal Ilana Freedhoff, Ph.D.' [Michal_Freedhoff@epw.senate.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; azota@gwu.edu; Chandler Randol [randol@eli.org]; Giddings, Daniel [giddings.daniel@epa.gov]; 'Daniel Rosenberg' [drosenberg@nrdc.org]; Heidi Brown Lewis [hlewis@lawbc.com]; Jeffery T. Morris, Ph.D. [jefferytmorris@outlook.com]; jsass@nrdc.org; Liz Hitchcock [lizhitchcock@saferchemicals.org]; Lorenz R. Rhomberg, Ph.D. [lrhomberg@gradientcorp.com]; lbergeson@lawbc.com; m_kirchhoff@acs.org; 'Melissa Perry' [mperry@gwu.edu]; Michael L. Dourson, Ph.D. [dourson@tera.org]; Richard E. Engler, Ph.D. [rengler@lawbc.com]; Robert M. Sussman [Ex. 6 Personal Privacy (PP)@comcast.net]; Scott Fulton, Esquire [fulton@eli.org]; Henry, Tala [Henry.Tala@epa.gov]; Collazo Reyes, Yvette [CollazoReyes.Yvette@epa.gov]
CC: Chad H. Howlin [chowlin@lawbc.com]
Subject: TSCA Reform--Four Years Later SPEAKER INFORMATION
Attachments: Panel 1 Questions (00305204-7xAA4DC).docx; Panel 2 Questions (00305102-8xAA4DC).docx; Panel 3 Questions (00305608-2xAA4DC).docx

Colleagues,

We are very much looking forward to our virtual conference [TSCA Reform – Four Years Later](#) on Wednesday, June 24, 2020. By clicking on the link, you will see we have significantly expanded the speakers, and enhanced the program. (There are a few enhancement to the agenda that will be posted early on Monday.) As of close of business yesterday, we had about 400 registrants.

Thanks to all who participated in the calls this past week to prepare for our forthcoming panel discussions. In that regard, a few points are worth repeating:

- As a result of our discussions, revised questions for each panel are appended. Moderators are urged to use these questions or not. As we discussed, these questions are intended only to get the conversation started. Where the conversation goes is up to the panel.
- Panel 1 now includes, in addition to OPPT Office Director Yvette Collazo, Deputy Director Mark A. Hartman. We are very appreciative of Mark's participation.
- Panel 2 now includes Dr. Michal Freedhoff. Dr. Freedhoff needs no introduction and her engagement in TSCA reform is extraordinary. We are very appreciative of Dr. Freedhoff's participation.
- Similarly, Deputy Assistant Administrator, OCSPP, David B. Fischer, will participate in Panel 3. David's understanding of and contributions to TSCA implementation are most welcome and we are grateful for David's participation.
- Each panel is 90 minutes. In terms of format and as discussed, we suggest each moderator frame the panel discussion and introduce each panelist, and then allow each panelist approximately 3-4 minutes to make an opening statement. The panel discussion should last around 50 minutes or so to allow time for audience Q&A. Chandler or his ELI colleagues will forward audience questions that are electronically directed to the GoToWebinar platform to the panel moderator and the panel moderator will direct them accordingly.
- As we discussed, we are mindful of the somewhat abrupt end to any virtual panel. To enable participants to "debrief" after each panel, continue the conversation, or compare notes on how the panel went, we have scheduled a Zoom "green meeting" room for panelists to join after sessions if they wish. The same meeting link will be used all day.

TSCA at 4 Panelists' Lounge:

<https://lawbc.zoom.us/j/95955000284>
Password: 819100

Since security has been tightened, participants will stay in a "waiting room" until the host allows them entry to the meeting. My colleague, Heidi Lewis, will monitor the Zoom meeting near the end of each TSCA at 4 session to admit presenters from the waiting room. Thank you, Dr. Perry, for this excellent suggestion.

- You need NOT register to participate in the conference. You do, however, need to join the GoTo Webinar 15 minutes before the scheduled start time of your panel to participate in the panel. You should have received a GoToWebinar email from ELI. **IF YOU DID NOT RECEIVE A GOTOWEBINAR EMAIL** from ELI, please email Chandler Randol, randol@eli.org to obtain one.
- We have prepared speaker bios and the document will be posted on Monday, Other meeting materials are posted as they are received. If you have materials you would like registrants to review, please send them to Chandler.
- If anyone has other questions, please feel free to call or email me anytime. My contact information is below.

Thanks to all,

Lynn

LYNN L. BERGESON

MANAGING PARTNER

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Questions for Panel 1 -- TSCA Implementation: Where Are We Now?

1. **Big Picture Accomplishments over the Past Four Years.** In her keynote remarks, we understand that Assistant Administrator Dunn will be focusing primarily on the current and coming work of the Agency that is occurring in 2020. It would be helpful for the panel to step back and discuss what EPA has accomplished in the past four years since the passage of the Lautenberg Act from each of the panelists' diverse perspectives.
2. **Risk Evaluation Process.** EPA is often questioned about why EPA does not simply "ban" chemicals and criticized for how long the risk evaluation process takes. Just last week, Senator Tester asked why asbestos has not been banned since the passage of the Lautenberg amendments. Perhaps Mark could explain, in broad terms, the risk evaluation process and why it "takes so long," and others may express their views on the topic.
3. **Risk Management Issues.** Once EPA completes a risk evaluation and risk has been found, what happens next?
4. **Path Forward on Existing Chemicals.** Broadly, what are some lessons learned from the panelists' experiences with the "First 10" -- and what are the implications for the next 20 high-priority chemicals?
5. **Use of Other Statutory Authorities beyond Amended TSCA.** TSCA is not the only legislation that has impacts on chemical management. What is the role of other statutory authorities, and how do they intersect with TSCA?
6. **Public Perception.** What evidence is there that the American public believes industrial chemical safety has or has not improved as a result of EPA's implementation efforts?
7. **New Chemicals.** Section 5 (new chemicals) got off to a challenging start. Certain changes to the program were necessitated by Lautenberg, some of which were quite unexpected. What changes has EPA made, and how do panelists feel about their implementation?
8. **Pollution Prevention Act.** To what extent is the new chemicals program meeting the policy ambitions of the Pollution Prevention Act in encouraging pollution prevention through the introduction of safer and greener new chemicals?
9. **Looking Back.** In looking back, what has surprised you the most with TSCA implementation?
10. **Stakeholder Engagement.** Stakeholder engagement has been considerably broader and greater than was generally the case over the history of old TSCA. What could stakeholders do better or differently that would improve TSCA implementation? What steps might EPA take to improve the coherence of and logical interconnections in stakeholder engagement?

11. **PFAS.** Per- and polyfluoroalkyl substances (PFAS) have received a great deal of attention over recent years from states, Congress, and across EPA. Recognizing the important early role that EPA's Office of Chemical Safety and Pollution Prevention's (OCSPP) voluntary and regulatory efforts on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) had in the first decade of this century in largely eliminating production and use of these chemicals, what do you foresee for the TSCA program concerning new and existing chemical PFAS substances into the future? Will the center of gravity in EPA continue to focus on other program areas (*e.g.*, water and waste programs), or will TSCA and OCSPP play an increasing role? If the latter, what might we expect to see regarding TSCA?

Questions for Panel 2

1. Lautenberg created a new process for identifying and evaluating existing chemicals to assess their potential for posing unreasonable risks. How is the new process working?
2. If the process is working as intended, are any refinements needed?
3. If the process is not working as well as it could, are the reasons for that systemic or are they growing pains?
4. Is the evolution of EPA's approach a natural and necessary part of the interpretation and implementation of new statutory requirements?
5. In risk evaluations, how should the U.S. Environmental Protection Agency (EPA) approach and address legacy uses? As background exposures?
6. Testing -- Lautenberg imposes tight deadlines on completion of prioritization and risk evaluation once those processes have been initiated. What approaches might EPA consider to increase the efficiency and effectiveness of efforts to identify and timely fill data needs and better to inform EPA in these processes?
7. EPA has put considerable effort into meeting the requirements under Lautenberg for reducing vertebrate animal testing. What is your appraisal of the current situation, both generally and with regard to specific methods? How should EPA focus its efforts over the coming years? Is EPA optimizing the use of practicable and scientifically justified new approach methodologies (NAM), particularly as components in testing tiers?
8. New chemical categories are thought by many to be out of date, and most would agree that they do not represent the "best available science." EPA is making progress on updating the new inhalation categories. How high a priority should it be for EPA to refresh and strengthen the scientific basis for the other categories? If it is a priority, what approaches and strategies should EPA consider in such an effort?
9. Risk evaluations: Is EPA optimizing "best available data"? If not, what might EPA do to improve the situation?
10. A number of peer reviews by EPA's Science Advisory Committee on Chemicals (SACC) have pointed to the limited and, in the committee's view, inadequate exposure information that is available in risk evaluations. Do you agree with their concerns, and if so, what steps should EPA be considering to improve the situation going forward?

Questions for Panel 3

1. What is the biggest unresolved TSCA policy issue, and how can we work together to address it?
2. What are the key regulatory and/or policy barriers to realizing the promise of the TSCA amendments, and how do we overcome those barriers?
3. Since June 2016, what best practices have emerged that we should do more of to advance TSCA implementation?
4. New chemicals must meet standards as a condition of commercialization that their existing chemical counterparts generally need not meet (unless they are themselves the subject of EPA review and action under TSCA Sections 5 or 6). How do you believe EPA should take into consideration in the new chemical review process the benefits associated with reduced-risk chemicals?
5. Recognizing EPA's use of TSCA Section 8(a) chemical data reporting (CDR) data and that EPA has recently issued a TSCA Section 4 order for testing of PV-29, should EPA take greater advantage of its TSCA Section 8 information gathering and Section 4 testing authorities to support the prioritization, evaluation, and where appropriate, regulation of chemicals, *i.e.*, to increase the body of information that is "reasonably available" to the Administrator? Given the tight time line imposed under Lautenberg for completing these processes once initiated, please discuss how EPA might approach the timing of efforts to identify and fill hazard and exposure data needs to better inform these processes? Also discuss the role of regulatory or administrative tools (rules, orders, and subpoenas) versus voluntary collaborative efforts?
6. What is the role of the TSCA Section 4(e) Interagency Testing Committee (ITC) under reformed TSCA? Has it changed with the reform of TSCA?
 - a. Regardless, should the ITC have a greater role in identifying chemicals in need of testing than it has played over the past ten years?
 - b. Considering the procedures that are set up that allow EPA to issue direct final TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) reporting and Section 8(d) Health and Safety Data Reporting rules for chemicals recommended for testing by the ITC, should the ITC be engaged to help support EPA in its prioritization, evaluation, and regulation of chemicals? Is there a role for the ITC in pre-prioritization efforts, and if so, what might that role be, both in the short term and with regard to helping EPA to "see over the horizon"?

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 6/15/2020 11:23:09 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; azota@gwu.edu; Chandler Randol [randol@eli.org]; Giddings, Daniel [giddings.daniel@epa.gov]; 'Daniel Rosenberg' [drosenberg@nrdc.org]; Heidi Brown Lewis [hlewis@lawbc.com]; Jeffery T. Morris, Ph.D. [jefferytmorris@outlook.com]; jsass@nrdc.org; Liz Hitchcock [lizhitchcock@saferchemicals.org]; Lorenz R. Rhomberg, Ph.D. [lrhomberg@gradientcorp.com]; lbergeson@lawbc.com; m_kirchhoff@acs.org; 'Melissa Perry' [mperry@gwu.edu]; Michael L. Dourson, Ph.D. [dourson@tera.org]; Richard E. Engler, Ph.D. [rengler@lawbc.com]; Robert M. Sussman [Ex. 6 Personal Privacy (PP)]@comcast.net]; Scott Fulton, Esquire [fulton@eli.org]; Henry, Tala [Henry.Tala@epa.gov]; Collazo Reyes, Yvette [CollazoReyes.Yvette@epa.gov]
Subject: TSCA Reform: Four Years Later Panel Questions.
Attachments: Panel 1 Questions (00305204-2xAA4DC).docx; Panel 2 Questions (00305102-4xAA4DC).docx; Panel 3 Questions (00305202-2xAA4DC).docx

Good Evening Colleagues,

As noted in our email of last week, appended are "starter questions" for each of the panels at next week's TSCA at 4 program. These are by no means the questions any panel needs to consider; they are intended to jump start the discussion.

Chad Howlin will be scheduling three calls for later this week, one for each panel. We can discuss then. Please respond to Chad's email so we can get some meetings set up quickly. I realize not everyone receiving this email is actually scheduled to participate in a panel so if you are not, please feel free to ignore this email.

Thanks!

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Questions for Panel 1 -- TSCA Implementation: Where Are We Now?

1. Overall, has new TSCA achieved Congress' goals in amending TSCA?
2. EPA has largely timely met the statutory deadlines for the many and often complex mandated actions imposed by Congress. Recognizing that the actions taken by EPA represent the first of what will likely be many rounds of regulatory measures under the amended law, to what extent has EPA fulfilled the underlying intent of the broad array of these requirements? These requirements include those under Sections 4 (strategic plan for alternative test methods), 5 (PMN reviews), 6 (procedural rules, prioritizations and risk evaluations, and regulatory actions on persistent, bioaccumulative, and toxic (PBT) substances, 8 (inventory notification rule and active chemical designation, small business definition, mercury inventory), review of confidential business information (CBI) claims, and 26 (fees)?
3. What evidence is there that the American public believes industrial chemical safety has or has not improved as a result of EPA's implementation efforts?
4. Section 5 (new chemicals) got off to a rocky start. How do you think the program is functioning now?
5. What specific changes has EPA made to the new chemical program that have proven effective in meeting the goals and objectives under the amended law? What specific changes made by EPA have fall fallen short in this regard?
6. To what extent is the new chemicals program meeting the policy ambitions of the Pollution Prevention Act in encouraging pollution prevention through the introduction of safer and greener new chemicals?
7. In looking back, what has surprised you the most with TSCA implementation?
8. Stakeholder engagement has been considerably broader and greater than was generally the case over the history of old TSCA. What could stakeholders do better or differently that would improve TSCA implementation? What steps might EPA take to improve the coherence of and logical interconnections in stakeholder engagement?
9. Per- and polyfluoroalkyl substances (PFAS) have received a great deal of attention over recent years from states, Congress, and across EPA. Recognizing the important early role that EPA's Office of Chemical Safety and Pollution Prevention's (OCSPP) voluntary and regulatory efforts on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) had in the first decade of this century in largely eliminating production and use of these chemicals, what do you foresee for the TSCA program concerning new and existing chemical PFAS substances into the future? Will the center of gravity in EPA continue to

focus in other program areas (*e.g.*, water and waste programs), or will TSCA and OCSPP play an increasing role? If the latter, what might we expect to see regarding TSCA?

Questions for Panel 2

1. In risk evaluations, how should EPA address legacy uses? As background exposures?
2. Testing -- what is the most efficient way for EPA to identify and fill data gaps in time for EPA to consider the data in prioritization and risk evaluation?
3. Chemical Data Reporting (CDR): Any thoughts on petitions to remove exemptions for certain substances?
 - a. Are CDR data necessary to complete a risk evaluation?
4. New chemical categories are woefully out of date. EPA is making progress on updating the new inhalation categories. How high a priority should it be for EPA to refresh the other categories (especially with respect to adding non-animal testing to the testing tiers)?

Questions for Panel 3

1. Given the U.S. District Court for the Northern District of California's holding in the fluoride-related case that petitioners need not address all conditions of use in petitions for TSCA Section 6(a) rules, are there thoughts on whether EPA could face an increasing number of petitions requesting that EPA address a narrow use/narrow uses of particular concern? Does this interpretation of "conditions of use" conform with TSCA Section 21 before TSCA reform? Although some latitude might be understandable for purposes of citizen petitions, might this holding by the court be applied elsewhere in interpreting the law and what that might mean?
2. Recognizing that TSCA Section 6(a) provides authority for geographically specific regulations and in light of the court's holding, can the TSCA Section 21 process under amended TSCA be used to address environmental justice issues, for example, associated with a chemical of concern or a given use or exposure situation in a specific neighborhood or other limited geographic region?
3. Concerning EPA's new chemical reviews and considering what has been termed "new chemical bias," where new chemicals must meet standards as a condition of commercialization that their existing chemical counterparts generally need not meet (unless they are themselves the subject of EPA review and action under TSCA Sections 5 or 6), how do you believe EPA should take into consideration benefits associated with reduced-risk chemicals?
4. Recognizing EPA's use of TSCA Section 8(a) chemical data reporting (CDR) data and that EPA has recently issued a TSCA Section 4 order for testing of PV-29, should EPA take greater advantage of its TSCA Section 8 information gathering and Section 4 testing authorities to support the prioritization, evaluation, and where appropriate, regulation of chemicals, *i.e.*, to increase the body of information that is "reasonably available" to the Administrator? Given the tight time line imposed under Lautenberg for completing these processes once initiated, please discuss how EPA might approach the timing of efforts to identify and fill hazard and exposure data needs to better inform these processes? Also discuss the role of regulatory or administrative tools (rules, orders, and subpoenas) versus voluntary collaborative efforts?
5. What is the role of the TSCA Section 4(e) Interagency Testing Committee (ITC) under reformed TSCA? Has it changed with the reform of TSCA?
 - a. Regardless, should the ITC have a greater role in identifying chemicals in need of testing than it has played over the past ten years?
 - b. Considering the procedures that are set up that allow EPA to issue direct final TSCA Section 8(a) Preliminary Assessment Information Rule (PAIR) reporting and Section 8(d) Health and Safety Data Reporting rules for chemicals

recommended for testing by the ITC, should the ITC be engaged to help support EPA in its prioritization, evaluation, and regulation of chemicals? Is there a role for the ITC in pre-prioritization efforts and, if so, what might that role be, both in the short term and with regard to helping EPA to “see over the horizon”?

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 7/23/2019 1:25:13 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
Subject: RE: Do you have Nancy's slides from last year's Webinar? If so can you send them.
Attachments: TSCA at 2. An Update on Implementation and Hot Topics (00245239-3xAA4DC)....pdf

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Dunn, Alexandra [mailto:dunn.alexandra@epa.gov]
Sent: Tuesday, July 23, 2019 9:09 AM
To: Lynn L. Bergeson
Subject: Do you have Nancy's slides from last year's Webinar? If so can you send them.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
(202) 564-2910
dunn.alexandra@epa.gov



BERGESON & CAMPBELL PC

**2018 Bloomberg BNA/
Bergeson & Campbell, P.C.
Chemical Policy Summit Series**

**TSCA at 2: An Update on
Implementation and Hot Topics**

June 25, 2018

Program

Opening -- **Lynn L. Bergeson**
Managing Partner
Bergeson & Campbell, P.C.

Agency Update -- **Nancy B. Beck, Ph.D., DABT®**
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

Key Section 5 Concerns -- **Misty L. Bogle**
Global Product Stewardship Manager
Vertellus

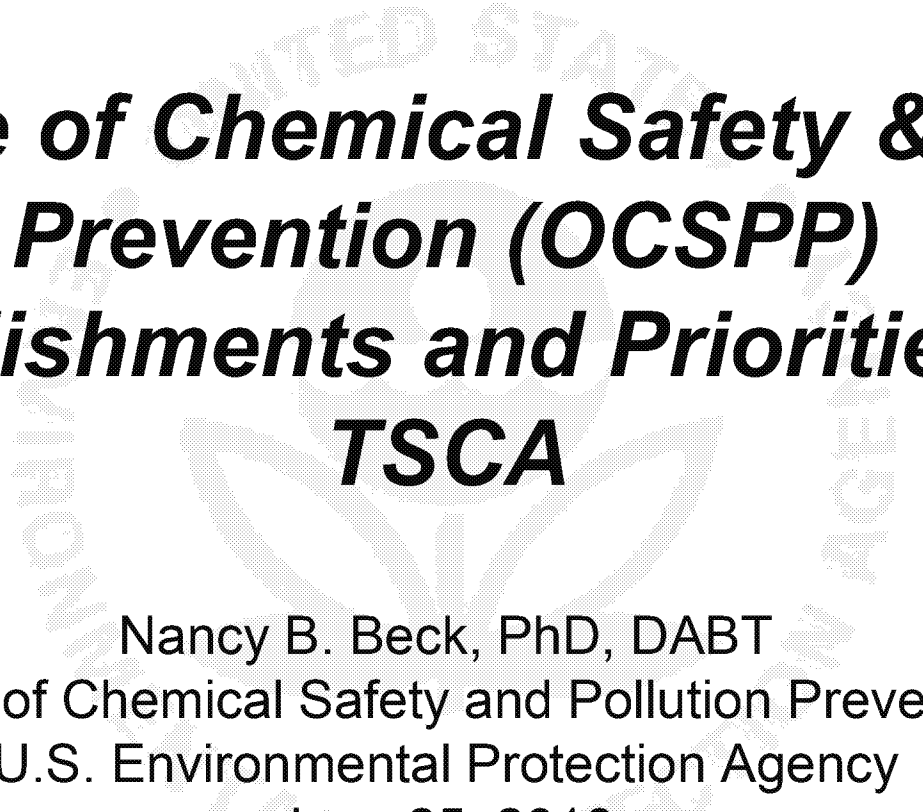
Key Section 5 Concerns -- **Michael Gould**
EH&S Committee Chairman
RadTech North America

Questions

Close



Nancy B. Beck, Ph.D., DABT®
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency



EPA Office of Chemical Safety & Pollution Prevention (OCSPP) Accomplishments and Priorities under TSCA

Nancy B. Beck, PhD, DABT
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency

June 25, 2018

beck.nancy@epa.gov



Toxic Substances Control Act (TSCA)

Year 2 Accomplishments

- Addressing Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
- Dust-Lead Hazard Standards
- Final Mercury Reporting Rule
- Transparency and Confidential Business Information (CBI)
 - Unique Identifier
 - Generic Name Guidance
 - Expanded Access to CBI Guidance
- Alternative Strategy to Reduce Animal Testing





TSCA Year 2 Accomplishments

- New Chemicals Points to Consider
- Ten Problem Formulations
- Asbestos Significant New Use Rule (SNUR)
- Systematic Review Approach
- Proposed Fees Rule



Near-Term Priorities

- Methylene Chloride Final Rule
- Establishing a Fee Program
- Updating TSCA Chemical Substance Inventory
 - CBI Review Plan Rule
- Completing First Ten Chemicals Risk Evaluations
- Selecting the Next 40 Chemicals for Prioritization
- Addressing PBTs
- Refining New Chemicals Review



Misty L. Bogle
Global Product Stewardship Manager
Vertellus

Conditions of Use (COU)

- **Section 3 Definition:** "... the circumstances, as determined by [EPA], under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed..."
- The Office of Pollution Prevention and Toxics (OPPT) considered COU in the past, including foreseeable COU, and would impose restrictions (e.g., use limitations, water release limitations) to protect against those foreseen COU

Key Concerns

- If the U.S. Environmental Protection Agency (EPA) identifies a COU in which hazard is not low for health and for ecotoxicity (“low/low” cases), EPA is proposing regulation in nearly all cases
 - Basis: “somebody might” exceed the level of concern
 - Any conceivable vs. reasonably foreseeable

Key Concerns

- If EPA determines it is required to regulate under Section 5(f) or Section 5(e), it must do so “to the extent necessary” to protect against unreasonable risk
 - What is “the extent necessary”?
- Example for consideration:
 - An employer requires workers to wear gloves and gloves are provided to all workers
 - If EPA believes that a worker may choose not to wear the required gloves, is that a foreseeable COU and reasonable basis for a SNUR? Does adding a TSCA regulation in addition to the existing Occupational Safety and Health Administration (OSHA) regulation meet the “extent necessary” provision?

Key Concerns

- Notable outcomes
 - EPA requiring workplace protection duplicative to OSHA requirements
 - Very difficult to “test out” of restrictions -- absent testing to demonstrate low hazard, EPA imposes regulation

Case Study

BACKGROUND

- Stereoisomer -- non-specific analog already on TSCA Inventory
- Ester -- no releases to water, worker protections included
- Low Volume Exemption (LVE) granted -- no unreasonable risk
- Premanufacture Notification (PMN) application in June 2017
- Added aquatic test data
- Same controls in place
- PMN conditions – “not likely to present unreasonable risk”
- Concern about changes to COU -> non-5(e) SNUR

Questions for EPA

- Will we see additional guidance on the Agency's interpretation of "reasonably foreseen" circumstances in new chemical review?
- Can industry expect to be regulated in every case, unless our substance is completely non-hazardous?
- When will the backlog of non-5(e) SNURs be resolved?
- Feedback on issues of concern related to COU
- Could/should EPA revisit the option to consider relative risk?
 - Because EPA no longer considers relative risk in new chemical review, less hazardous new chemicals are more highly regulated than more hazardous existing chemicals



Michael Gould
EH&S Committee Chairman
RadTech North America

Business Concerns with SNURs

- Consent order or non-order SNUR trigger
 - Section 12(b) export notification if substance present at >1 percent
 - Supply chain communication to all recipients
 - Recordkeeping requirements apply to all levels of supply chain
 - Lower reporting thresholds for Chemical Data Reporting (CDR)
- Some companies prohibit purchasing a substance with a SNUR due to a perception of enhanced risk

Current Forecast on SNURS

- Many more SNURs in our future
 - Recent analysis shows:
 - About 5 percent of initial determinations are not likely
 - 11.5 percent of final determinations are not likely
 - Is this trend reversible?
- Necessity of SNURs
 - Role of workplace standards
 - Is EPA coordinating with OSHA?

Case Study

BACKGROUND

- Pre-amended TSCA, PMN filed for substance regulated under LVE
 - Substance is low molecular weight polymer of a discreet chemical substance with known toxicity concerns
- PMN initially dropped, but pulled back into re-evaluation after amended TSCA passed

CURRENT STATUS

- Conclusion of re-evaluation under amended TSCA included certain restrictions
 - Including concentration limitation for imported products
 - Concentration limitation makes it impossible for manufacturer to import raw material
- Re-evaluation also focuses on toxicity of parent compounds versus final product

Question for EPA

- Does EPA evaluation take into account the fact that by making the discreet substance into a polymer, the substance has less exposure potential?
 - Less accessible at the cellular level
 - More secure in final cured articles

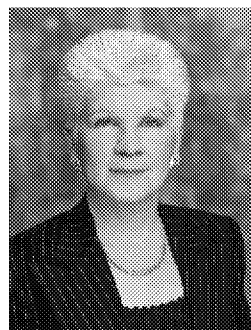
Related SNUR Issues

- Significant delays, especially in SNUR publication
 - Order SNURs -- no reason to delay; required by statute, restrictions established in consent order
 - Non-order SNURs -- authority has been questioned
- Section 5(e) SNURs must be prompt
- Fish or cut bait on non-order SNURs
- Creative solutions when hazards can be addressed by limiting how substance is manufactured
 - Proposal to create new Inventory flag for chemicals with workplace exposure concerns
- Example for consideration: The EPA conservative model predicts exposure a level order of magnitude below a chemical's concentration of concern (COC)
 - Is it foreseeable that COC could be exceeded?
 - Is this a reasonable basis for a SNUR?

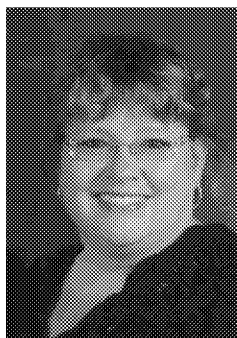
Questions



Nancy B. Beck, Ph.D., DABT®
Deputy Assistant Administrator
Office of Chemical Safety and
Pollution Prevention
EPA



Lynn L. Bergeson
Managing Partner
Bergeson & Campbell, P.C..



Misty L. Bogle
Global Product
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Michael Gould
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Thank You

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lbergeson@lawbc.com
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<http://www.tscablog.com/>

Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]
Sent: 7/22/2019 6:55:38 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
Subject: RE: Letter
Attachments: 00270863.pdf

Here you go!

LYNN L. BERGESON
MANAGING PARTNER
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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Dunn, Alexandra [mailto:dunn.alexandra@epa.gov]
Sent: Monday, July 22, 2019 12:48 PM
To: Lynn L. Bergeson
Subject: RE: Letter

Can your office please resend the letter? I deleted it and cannot pull back up.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
(202) 564-2910
dunn.alexandra@epa.gov

From: Lynn L. Bergeson <lbergeson@lawbc.com>
Sent: Monday, July 15, 2019 10:49 AM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>
Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>
Subject: RE: Letter

Thanks!

LYNN L. BERGESON
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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037
T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Dunn, Alexandra [mailto:dunn.alexandra@epa.gov]
Sent: Monday, July 15, 2019 10:37 AM
To: Lynn L. Bergeson
Cc: Richard E. Engler, Ph.D.
Subject: Re: Letter

Thanks for the letter. Will follow up.

Sent from my iPhone

On Jul 15, 2019, at 9:20 PM, Lynn L. Bergeson <lbergeson@lawbc.com> wrote:

Good Morning Alex:

We wanted to give you a heads-up on this case. After reviewing the study, RAD and Todd recommended low hazard and to rescind the SNUR. We understand that Dr. Henry has disagreed and has sent the hazard assessment back to RAD. We do not yet have the updated hazard and health assessments to know the basis of the disagreement. .

Rich has requested a status update from the program manager, but the assessment is not yet forthcoming. We may need to elevate this case given Jeff's absence.

Thanks,

Lynn

LYNN L. BERGESON
MANAGING PARTNER

BERGESON & CAMPBELL PC

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<Letter to AA Dunn re. polysaccharide (Sanitized Version) (00270863xAA4DC).pdf>

Sanitized Version

May 21, 2019

Via Hand Delivery

The Honorable Alexandra Dapolito Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave., N.W.
MC 7101M
Washington, D.C. 20460

Re: Polysaccharide Premanufacture Notice

Dear Assistant Administrator Dunn:

We are writing to express our concern over the way that the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) has addressed a premanufacture notice (PMN) submitted by [REDACTED] in 2016.

[REDACTED] submitted a PMN in 2016 for a polysaccharide derived enzymatically from simple sugars; the PMN was assigned Case Number P-16-0581. The polysaccharide is intended to be used as an additive in various plastic, paper, or other industrial applications to provide state-of-the-art material performance while using a substance that is inherently renewable and biodegradable. The biodegradability is especially important when used as an additive in these and other applications. Rapidly growing interest from consumers, brand owners, non-governmental organizations (NGO), and governmental organizations to address the growing global plastic pollution crisis and sustainable management of single use products is accelerating demand for new material solutions. This [REDACTED] polysaccharide is the basis of a platform that will add new innovative options to address this crisis. Swift action by EPA will enable first commercial applications by [REDACTED] and will accelerate replacement of non-biodegradable plastics that are contributing to the global plastic pollution crisis.

EPA's review focused on concerns for lung effects for workers. OPPT did not predict any aquatic toxicity, nor did it identify any hazards other than the potential for lung overload for poorly soluble particles (PSP).¹ As OPPT is aware, lung overload occurs when

¹ Structure Activity Team (SAT) Report for P-16-0581 (Jan. 6, 2018); TSCA Section 5(a)(3) Determination for Premanufacture Notice (PMN) P-16-0581 (October 9, 2018), available

The Honorable Alexandra Dapolito Dunn

May 21, 2019

Page 2

exposure to PSPs exceeds the lung's ability to clear the particles. In response to EPA's concerns and the protracted review process, about one and a half years after the original submission, [REDACTED] amended the PMN to remove a grinding step in which large, non-respirable particles are ground down to a nominal size of 17-20 microns, with a distribution that has slightly more than five percent of particles at less than ten microns. Particles of this size are desired for use by downstream customers in the large majority of their polymer, composite, and fiber compounding applications, but, the size of these particles makes them respirable (able to penetrate the deep lung). For this reason, action was taken by [REDACTED] to first gain EPA approval to manufacture and market the un-ground polysaccharide for those limited opportunities for which a larger particle size will suffice to bring the desired technical effects.

[REDACTED] then continued to negotiate with EPA to identify a path for regulatory approval for production of the ground polysaccharide, as the ground material represents the greatest opportunity for this innovation to help address the global plastics pollution crisis. Despite the fact that this severely curtails the commercial potential for the product, [REDACTED] agreed to limit production to a larger, non-respirable size. Here, EPA no longer had a concern, but grinding was still reasonably foreseeable, so OPPT proposed a "not likely based on SNUR," that is, to propose a Significant New Use Rule (SNUR) prohibiting grinding below ten microns and making a "not likely to present unreasonable risk" determination. While EPA was working out the details on issuing the SNUR, [REDACTED] worked with OPPT's Risk Assessment Division (RAD) scientists to find an alternative to EPA's proposed 90-day inhalation testing in rats. [REDACTED] and RAD agreed that [REDACTED] would perform an *in vitro* simulated lung fluid test to determine with a rigorous scientific approach if the product was, in fact, poorly soluble. Since [REDACTED] concluded the testing after the comment period on the proposed SNUR closed, but before the final SNUR was published, it contacted staff in the Chemical Control Division (CCD) to request that OPPT delay promulgating the SNUR in final until RAD had reviewed the test results. The thinking was that if RAD concluded, as [REDACTED] had, that the results demonstrated that the polysaccharide is soluble in simulated lung fluid, EPA's sole concern would be addressed, the substance would then be considered low hazard, and no regulatory action would be necessary. In that case, publishing the SNUR in final, only to rescind it when the study review was complete, would be a significant waste of OPPT resources and would further delay [REDACTED]'s expansion of its commercial opportunities and the adoption of this innovative solution to help address the global plastics pollution crisis.

at https://www.epa.gov/sites/production/files/2018-10/documents/p-16-0581_determination_non-cbi_final.pdf.

The Honorable Alexandra Dapolito Dunn

May 21, 2019

Page 3

██████████ and its representatives from Bergeson & Campbell, P.C. (B&C[®]) spoke with or e-mailed the case manager, the team lead in charge of the SNUR, the Branch Chief of the New Chemicals Management Branch, and finally Dr. Tala Henry, Acting Deputy Director of OPPT. Dr. Henry stated that even if RAD's assessment demonstrated biosolubility, RAD could not conclude that the substance was low hazard without *in vivo* testing, despite the fact that biosolubility testing is: (1) identified as the first tier of testing in the Poorly Soluble Particulate Category, a category to which ██████████ has now demonstrated that the polysaccharide does not fall; and (2) RAD agreeing that the *in vitro* method proposed by ██████████ would inform RAD's view of the hazard. Despite ██████████'s best efforts, the final SNUR was promulgated prior to RAD completing its review of the biosolubility study. Furthermore, ██████████ found out about the promulgation when the SNUR was made public. Despite our close and repeated contact with OPPT, surprisingly management neglected to inform ██████████ of OPPT's decision prior to promulgation.

Since the SNUR was promulgated, ██████████ convened a conference call with OPPT toxicologists and risk assessors to discuss RAD's view of the study. That call revealed that, although indications are that RAD agrees that the *in vitro* study did demonstrate solubility in simulated lung fluid, it is not clear what the outcome will be out of the study review. ██████████ is still waiting for RAD's updated health assessment. Based on our limited understanding, OPPT seems to be proposing to modify, rather than rescind, the SNUR, despite the study having demonstrated that the substance is not a PSP.

██████████ has been exceedingly patient and has negotiated with OPPT in good faith. OPPT, on the other hand, seems to be insistent upon regulating the substance, regardless of data that support that the substance does not present unreasonable risk under the reasonably foreseeable conditions of use simply because the substance does not exhibit the properties that EPA predicted (*i.e.*, that it is a PSP).

██████████ respectfully requests that OPPT provide clarity on:

1. RAD's view of the biosolubility study. If RAD disagrees with ██████████'s interpretation of the study, the basis for that disagreement;
2. Why RAD would agree to consider *in vitro* testing in lieu of *in vivo* testing if the *in vitro* testing was never going to be sufficient to demonstrate low hazard. If RAD needed both *in vitro* and *in vivo* testing to conclude that the

The Honorable Alexandra Dapolito Dunn
May 21, 2019
Page 4

substance is low hazard, RAD should have so stated when discussing the *in vitro* testing.

3. If RAD now views the product as biosoluble, why OPPT is proposing modifying, rather than rescinding, the SNUR. If the substance is indeed biosoluble then there are no hazards that would require EPA to protect against with a SNUR.
4. OPPT's proposed path to remedy its hasty promulgation of a SNUR when there were data that might demonstrate that the SNUR was not necessary that was days or weeks away from being reviewed; and
5. Why OPPT did not inform [REDACTED] of its decision to proceed with publishing the SNUR prior to doing so (except to deny [REDACTED] the opportunity to further advocate for its position).

Finally, [REDACTED] respectfully requests a meeting with you and any staff and management from OPPT or the Office of Chemical Safety and Pollution Prevention (OCSPP) that you feel should attend.

Sincerely,



Richard E. Engler, Ph.D.
Director of Chemistry

cc: Lynn L. Bergeson, Esquire (via e-mail)

Message

From: Richard E. Engler, Ph.D. [rengler@lawbc.com]
Sent: 5/22/2019 10:11:05 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
CC: lbergeson@lawbc.com
Subject: Letter regarding a recent PMN decision
Attachments: 00270863.pdf

Alex:

Attached is a sanitized copy of a letter delivered yesterday to the OPPT Confidential Business Information Center (CBIC).

B&C and its client look forward to discussing this issue further.

Rich

RICHARD E. ENGLER, PH.D.
DIRECTOR OF CHEMISTRY
BERGESON & CAMPBELL PC
2200 Pennsylvania Avenue, NW, Suite 100W | Washington, D.C. 20037
T: 202-557-3808 | F: 202-557-3836 | lawbc.com

Sanitized Version

May 21, 2019

Via Hand Delivery

The Honorable Alexandra Dapolito Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave., N.W.
MC 7101M
Washington, D.C. 20460

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The Honorable Alexandra Dapolito Dunn

May 21, 2019

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The Honorable Alexandra Dapolito Dunn
May 21, 2019
Page 3

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██████████ respectfully requests that OPPT provide clarity on:

1. RAD's view of the biosolubility study. If RAD disagrees with ██████████'s interpretation of the study, the basis for that disagreement;
2. Why RAD would agree to consider *in vitro* testing in lieu of *in vivo* testing if the *in vitro* testing was never going to be sufficient to demonstrate low hazard. If RAD needed both *in vitro* and *in vivo* testing to conclude that the

The Honorable Alexandra Dapolito Dunn
May 21, 2019
Page 4

substance is low hazard, RAD should have so stated when discussing the *in vitro* testing.

3. If RAD now views the product as biosoluble, why OPPT is proposing modifying, rather than rescinding, the SNUR. If the substance is indeed biosoluble then there are no hazards that would require EPA to protect against with a SNUR.
4. OPPT's proposed path to remedy its hasty promulgation of a SNUR when there were data that might demonstrate that the SNUR was not necessary that was days or weeks away from being reviewed; and
5. Why OPPT did not inform [REDACTED] of its decision to proceed with publishing the SNUR prior to doing so (except to deny [REDACTED] the opportunity to further advocate for its position).

Finally, [REDACTED] respectfully requests a meeting with you and any staff and management from OPPT or the Office of Chemical Safety and Pollution Prevention (OCSPP) that you feel should attend.

Sincerely,



Richard E. Engler, Ph.D.
Director of Chemistry

cc: Lynn L. Bergeson, Esquire (via e-mail)

Message

From: Franz, Christina [Christina_Franz@americanchemistry.com]
Sent: 3/22/2019 4:00:03 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]
Subject: ACC Documents on CBI
Attachments: CBI.BNA Article.pdf; ACC Perspectives on Amended TSCA Section 14 2016Finalcorrected.pdf; ACC Comments CBI Underlying Data 2018 06 06 Final.pdf

Dear Alex,

As I mentioned to you at GlobalChem, Mark Duvall of Beveridge & Diamond and I have worked together on confidential business information (CBI) issues under TSCA for many years and have developed a number of papers on the topic. We have shared these papers with EPA staff over the years. I have attached several key papers to share them now with you.

The first document was first prepared as a white paper and shared with EPA, but was shortly thereafter published in Bloomberg BNA in 2012. It is entitled *TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure*. While I recognize this paper was based on TSCA before it was amended and focuses primarily on confidential chemical identities in health and safety studies, it remains relevant in a number of important respects, e.g., it demonstrates that section 14(b) (most of which remains substantively unchanged) requires health and environmental information, such as *effects* information, to be available for disclosure, but not trade secret or confidential commercial information contained in those studies, and that section 14(a) protects trade secret and confidential commercial information in those studies from disclosure. In addition, this paper also provides significant historical context regarding congressional intent to protect CBI while, at the same time, providing the public with the health and environmental effects information or results of health and safety studies.

The second document is a letter to Barbara Cunningham, formerly with EPA, from me that discusses ACC's perspective on the appropriate interpretation that should be accorded to the LCSA amendments to TSCA's confidentiality provisions. The third and final document, *Comments of the American Chemistry Council on CBI Claims for Underlying Data for Health and Safety Studies under TSCA*, importantly establishes that EPA has discretion under section 14 to disclose the study reports submitted to EPA under TSCA and to withhold from public disclosure the data underlying those study reports.

I also wanted to let you know that ACC is working with its members to develop a potential compromise approach on voluntarily-submitted confidential foreign studies that would balance the public interest in access and the business interest in protecting their commercial value. That is the PV 29 issue. This project is in its early stages, but we will let you know when we can share ideas with EPA.

Mark Duvall and I would very much appreciate the opportunity to meet with you to discuss these documents with you once you have had an opportunity to review them. I will call your office late next week to see if we can arrange a time to do that.

Regards,

Christina Franz

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**Comments of the American Chemistry Council on CBI Claims for
Underlying Data for Health and Safety Studies under TSCA**

June 6, 2018

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EPA Should Accept CBI Claims for Underlying Data for Health and Safety Studies Submitted Under TSCA

EPA should balance the competing interests of public access to health and safety studies submitted under TSCA and protection of data compensation rights of the study submitters. It may do this under section 14 of TSCA by accepting substantiated claims that underlying data qualify for protection from disclosure under section 14(a). Disclosing the final study report while withholding the underlying data would provide the public with key information about the study while protecting the rights of data owners.

1. Legal Framework Allowing Protection of Underlying Data from Disclosure

EPA has discretion under section 14 to disclose the study reports for studies submitted under TSCA and to withhold from public disclosure the data underlying of those study reports that are submitted to EPA or which EPA otherwise obtains.

Subject to certain exceptions, the Freedom of Information Act (FOIA)¹ directs EPA to release to the public upon request the information submitted to it under its various statutes, including TSCA. Exemption 4, however, exempts from this mandatory disclosure obligation “trade secrets and commercial or financial information obtained from a person and privileged or confidential” (CBI).² This provision does not prohibit disclosure of such CBI, however.

Section 14(a) of TSCA as amended³ is a broad reverse-FOIA statutory provision that prohibits EPA from disclosing publicly information qualifying under FOIA exemption 4. Section 14(a) provides in part:

IN GENERAL.—Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

- (1) that is reported to, or otherwise obtained by, the Administrator under this Act; and
- (2) for which the requirements of subsection (c) are met.

Section 14(a) is itself subject to exceptions, however. Among them is section 14(b)(2), which provides in part:

INFORMATION FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—

¹ 5 U.S.C. § 552.

² 5 U.S.C. § 552(b)(4).

³ Amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), Pub. L. 114-182 (June 22, 2016).



- (A) any health and safety study which is submitted under this Act with respect to—
- (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or
 - (ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and
- (B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

The phrase “does not prohibit the disclosure” leaves to EPA the discretion and decision regarding the extent to which it will disclose a health and safety study. TSCA “does not prohibit the disclosure” of a health and safety study containing CBI due to section 14(b)(2). On the other hand, FOIA does not mandate the disclosure of a health and safety study qualifying as CBI due to paragraph (b)(4). The clear implication is that EPA has discretion to decide to what extent it will or will not disclose health and safety studies containing CBI, such as underlying data.

Section 14(b)(5) does not preclude EPA from exercising discretion to withhold underlying data. It provides:

CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information reported to or otherwise obtained by the Administrator under this Act that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

As noted above, the basis for EPA’s discretion would be its judgment in balancing competing interests, not because FOIA exemption 4 applies. EPA has previously exercised similar discretion in its regulations permitting CBI claims for chemical identity in health and safety studies submitted to support a PMN where a robust generic name is provided.⁴

2. The Competing Interests

When EPA exercises its discretion to decide to what extent to disclose a health and safety study, it should consider the competing interests at stake.

a. The Public Interest in Transparency of EPA Decision-Making

The public interest underlying section 14(b)(2) reflects the congressional intent that the basis for EPA’s decision-making under TSCA should be transparent. As amended, section 26(i) requires EPA to make its decisions based on the weight of the scientific evidence, and section 26(h) directs EPA to make its decisions in a manner consistent with the best available science. Section 26(j)(4) requires EPA to make available to the public a list of

⁴ 40 C.F.R. § 720.85(a)(2), (b)(3).



the studies considered when completing risk evaluations. Collectively, these provisions are advanced by making the health and safety studies on which EPA relies in its decision-making available to the public.

As discussed below, however, the public interest in access to underlying data for submitted studies is limited when balanced against the commercial interest in protecting competitive data from disclosure.

b. The Commercial Interest in Protecting Competitive Data from Disclosure

Congress expressed concern that CBI in health and safety studies not be disclosed. The Senate Report for S. 697 (the Senate version of what became the LCSA) cautioned:

The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.⁵

Sometimes the CBI in a health and safety study to be protected is the specific identity of the chemical substance that is the subject of the study.⁶ To make this point, Congress added to an exception to section 14(b)(2) a reference to information that reveals “molecular structures.” To ensure that the public would be able to understand studies for which the chemical identity is withheld as CBI, however, Congress in section 14(c)(1)(C) required a CBI claim for a chemical identity to include “a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public.”

Sometimes the CBI in a health and safety study to be protected is competitive information, such as “company name or address, financial statistics, and product codes used by a company.”⁷ In other instances the CBI in a health and safety study to be protected is, instead, the underlying data. EPA interprets “underlying data” to include “medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies.”⁸ Another term for “underlying data” is “raw data.”⁹ Sometimes underlying data

⁵ S. Rep. 114-67 (June 18, 2015) at 22.

⁶ Prior to enactment of the LCSA, EPA took the position that “[c]hemical identity is part of, or underlying data to, a health and safety study,” citing 40 C.F.R. § 716.3 (regulatory definition of “health and safety study”), and thus that confidential chemical identities in a health and safety study submitted under TSCA must be disclosed except as provided in the exception to section 14(b)(2). Industry disagreed with this position, arguing that chemical identities in health and safety studies could be withheld as CBI more broadly. In amending section 14(b), Congress recognized but did not resolve this dispute. See S. Rep. 114-67 at 22.

⁷ See 40 C.F.R. § 716.55(a)(4) (allowing study submitters under section 8(d) to omit such information from a study). The provision purports to rely on FOIA exemption 6 for information related to personal privacy, but is instead corporate information. Under the Supreme Court’s decision in *FCC v. AT&T, Inc.*, 562 U.S. 397, 408 (2011), however, corporate information is not eligible for exemption 6. The basis for this provision is actually exemption 4. This information is comparable to that excluded from the need for routine substantiation under section 14(c)(2).

⁸ 40 C.F.R. § 716.10(a)(4).

⁹ The TSCA Good Laboratory Practice (GLP) regulations define “raw data” in 40 C.F.R. § 792.3 as follows: “Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the



appears in lengthy appendices to health and safety studies, and at other times underlying data remains in separate files that may or may not be submitted with the study report that is submitted to EPA under TSCA.

Underlying data submitted to EPA under TSCA may qualify as CBI under FOIA exemption 4. While it may not qualify as a trade secret, it is “commercial ... information obtained from a person;” thus, if it is also “confidential,” it qualifies for FOIA exemption 4.¹⁰ Commercial information is “confidential” under Exemption 4 if its disclosure is likely “to cause substantial harm to the competitive position of the person from whom the information was obtained.”¹¹ EPA’s disclosure of raw data from a study submitted under TSCA, including disclosure to the study submitter’s competitors, can cause substantial competitive harm.¹²

Congress recognized in section 4 that health and safety studies can have commercial value to study submitters; thus, underlying data is “commercial information.” Section 4(c)(3)(A) provides that persons who submit health and safety studies required by EPA may be entitled to “fair and equitable reimbursement” from other companies benefiting by such submission. This provision, like the corresponding provisions in FIFRA, provides a mechanism by which the study owner is owed a measure of data compensation by others who benefit by submission of the study—typically, competitors—by avoiding the need to submit an equivalent study themselves.¹³

Even when the study report is disclosed, the underlying data may be “confidential,” i.e., its disclosure may result in substantial competitive harm to the study owner. Often, it is the availability of underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data generator of the value of its investment in the underlying data. A study submitted under TSCA may also need to be submitted to a foreign regulatory agency. If EPA has made the

result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. ‘Raw data’ may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.”

¹⁰ See, e.g., *Public Citizen Health Research Group v. FDA*, 185 F.3d 898 (D.C. Cir. 1999); *Public Citizen Health Research Group v. FDA*, 704 F.2 1280 (D.C. Cir. 1983).

¹¹ See *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 878 (D.C.Cir.1992) (en banc) (citing *National Parks*, 498 F.2d at 770).

¹² The raw data of a study not in the public domain qualifies as CBI when that data provides a commercial value to its owner. See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996) (drug manufacturer had an express expectation of confidentiality when it submitted raw data to the FDA in support of its application for approval of a new bovine growth hormone and the FDA maintained this data with the strictest confidence; disclosure of raw data is likely to substantially harm company's competitive position because this is the type of information that its competitors would use in order to develop their own version of this bovine growth hormone without incurring the research and development costs). Also see U.S. Department of Justice Guide on FOIA exemption 4 at

https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf

¹³ EPA has adopted rules implementing section 4(c)(3)(A) in 40 C.F.R. Part 791.

underlying data from that study public pursuant to section 14(b)(2), competitors would find it easier to use that study—without providing compensation to the original data owner to obtain data access or citation rights—to support their notification or registration of a substance under some foreign counterparts to TSCA.¹⁴

Any doubts EPA may have to whether underlying data qualifies as CBI may be resolved by review of the substantiation for its CBI claim provided by the study submitter under section 14(c)(3).

3. EPA Should Balance the Competing Interests by Allowing CBI Claims for Underlying Data

a. Section 14 Encourages Balancing of Competing Interests

Congress gave EPA discretion to decide to what extent to require health and safety studies to be disclosed, while protecting the CBI contained within those studies. This reflects the overall interest of Congress in section 14 of balancing the competing interests of transparency in EPA's decision-making and protection of CBI. The Senate Report explained:

In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.¹⁵

¹⁴ EPA under FIFRA requires persons citing a study owned by a third party to affirm that they have the study owner's permission to cite the study or have offered to pay data compensation to the study owner. 40 C.F.R. § 152.93(b). Similarly, REACH Article 30 requires SIEF members to pay compensation to other members who own studies needed for registration. Some other counterparts to TSCA do not have such a provision, however. For example, Japan, the Philippines, and Taiwan do not. For them, simply providing a copy of the study, however obtained, may be sufficient and there is no obligation to affirmatively demonstrate that the notifier or registrant has data access privileges. Competitors to the original data generator may be able to obtain full copies of a study from EPA because EPA disclosed it under section 14(b)(2). Without underlying data, however, the study may not be deemed to meet the data requirement.

¹⁵ S. Rep. 114-67 (2015) at 21.



b. The Public Interest in Underlying Data Is Limited Where that Underlying Data Qualifies as CBI

As noted above, the public interest in underlying data is limited in that the human health and environmental results of studies can be made public in a manner to meet the public interest while still protecting the competitive commercial value of underlying data. This may be concluded by EPA's general practice of accepting a study report without submission of underlying data.

Members of the public who may want to review a study on which EPA makes its decisions would presumably have access to the final study report. As described in EPA's GLP regulations, a final report includes extensive information about the study.¹⁶ Many studies submitted to EPA comply with the EPA GLP regulations, which require the Quality Assurance Unit to:

Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.¹⁷

Accordingly, members of the public generally have sufficient information to understand the basis for EPA's decision-making if they have access to the final report.

Admittedly, underlying data fits within the definition of "health and safety study." TSCA defines "health and safety" to include "underlying information,"¹⁸ and EPA has defined "health and safety study" to include "underlying data."¹⁹ The section 4 regulations, the section 8(d) regulations, and the PMN regulations require manufacturers to submit health and safety studies to EPA under some circumstances. Nevertheless, it is noteworthy that none of these regulations routinely requires study submitters to submit underlying data along with a final report. This is a clear indication that the final report communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting.²⁰

¹⁶ 40 C.F.R. § 792.185(a). All test rules and testing consent orders include a requirement to comply with the EPA GLPs, including this provision. Several significant new use rules provide that study reports must include the contents specified in that regulation. 40 C.F.R. §§ 721.537, 721.2122, 721.2584, 721.9928.

¹⁷ 40 C.F.R. § 792.35(b)(6).

¹⁸ TSCA § 3(8).

¹⁹ 40 C.F.R. §§ 716.3, 720.3(k), 725.3.

²⁰ ACC believes that making a final study report publicly available where the underlying data is CBI would comport with EPA's recent proposal regarding Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (April 30, 2018). In addition, where EPA relies on studies where the underlying data is CBI, EPA can access that underlying data to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If need be, EPA could contract with an independent third-party science reviewer to confirm those findings, although ACC believes this would likely be necessary only in unusual circumstances. EPA might also consider an approach followed under FIFRA where Data Evaluation Records of studies are made publicly available, but not the full study. See, e.g., <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf>



The section 4 GLP regulations require underlying data to be archived,²¹ but the testing requirements only call for submission of a final study report²² and reference to where the raw data are located.²³ EPA's FIFRA GLPs have a corresponding provision.²⁴ EPA does not routinely require persons subject to a section 4 testing requirement to submit underlying data along with a final report.

The section 8(d) regulations state:

In general, health and safety studies, as defined in § 716.3, on any substance or listed mixture listed in § 716.120, that are unpublished are reportable, i.e., must be submitted or listed. However, this requirement has limitations according to the nature of the material studied, so that: ...

(4) **Underlying data**, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies **do not have to be submitted** initially. EPA may request underlying data later under § 716.40.²⁵

Similarly, while the PMN regulations require submission of health and safety studies,²⁶ EPA does not require submission of underlying data, saying:

The data may be submitted in aggregate or summary form; underlying data, such as individual measurements, are not required.²⁷

Instead, EPA concluded that a study report will be sufficient:

If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.²⁸

c. Balancing the Competing Interests Favors Protection of Private Competitive Interests

EPA balanced the public and private interests in disclosure or non-disclosure of chemical identities in health and safety studies submitted to support PMNs, concluding that the private interest outweighed the public interest where the study submitter provided a sufficiently robust generic name.²⁹ Similarly, EPA should balance the public and private interests in disclosure or non-disclosure of underlying data submitted with studies where

²¹ 40 C.F.R. § 792.33(f) (study director must transfer all raw data to archives by the close of the study).

²² See, e.g., 40 C.F.R. §§ 799.5085(i), 799.5087(i), 799.5089(i).

²³ See, e.g., 40 C.F.R. §§ 795.120(e)(13), 797.1600(e)(12).

²⁴ 40 C.F.R. § 160.185.

²⁵ 40 C.F.R. § 716.10(a)(4) (emphasis added).

²⁶ 40 C.F.R. § 720.50.

²⁷ 48 Fed. Reg. 41132, 41136 (Sept. 13, 1993).

²⁸ 40 C.F.R. § 720.50(a)(3)(i).

²⁹ 40 C.F.R. § 720.85(a)(2), (b)(3); 48 Fed. Reg. 21722, 21739-40 (May 13, 1983).



the study submitter provides a final report which discusses most or all of the information called for by the TSCA GLP regulations and substantiates the CBI claim.

In adopting the section 8(d) exemption for underlying data, EPA explained:

The final requirements represent the Agency's effort to reduce the burden of the rule while still obtaining the most useful studies for our assessments. EPA received many good comments that allowed the Agency to identify the studies that were most burdensome to submit and least useful for its assessments. Therefore, the Agency has added to the exemptions originally proposed. The final rule has the following overall exemptions: ... (7) underlying data such as medical records, monitoring data, and lab notebooks (unless the EPA requests the data later, by personal letter).³⁰

In its words, EPA considers underlying data to be “least useful for its assessments.” EPA reserved the possibility that it might need underlying data, in which case it could request the underlying data by letter, facility archive inspection/audit, or, potentially, by subpoena.³¹ In practice, however, EPA has rarely, if ever, requested underlying data. This long-time experience is strong evidence that, generally, the scientific need for underlying data is low for studies conducted according to GLP regulations. This suggests that the public interest in having access to underlying data for health and safety studies where a final report of a GLP study is provided is also low.

In contrast, the private interest in preserving the compensability of underlying data for studies when submitted under foreign counterparts to TSCA is high. Underlying data can qualify as CBI, and Congress put a premium on preserving CBI in health and safety studies.

EPA should weigh the competing interests and conclude that it should not disclose underlying data submitted or otherwise obtained under TSCA where the study submitter can substantiate its CBI claim and it provides a study report.

³⁰ 47 Fed. Reg. 38780, 38781 (Sept. 2, 1982).

³¹ See 40 C.F.R. § 716.40.





September 15, 2016

Barbara Cunningham (7401M)
Deputy Director for Management and Pollution Prevention
Office of Pollution Prevention and Toxics
Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Initial Evaluation of the Amended TSCA Confidentiality Provisions

Dear Barbara:

On behalf of the American Chemistry Counsel (ACC), I thought it would be useful to share with EPA ACC's initial ideas on how the various provisions of the amendments made to the Toxic Substances Control Act (TSCA) by the Lautenberg Chemical Safety Act (LCSA) should be interpreted. We would appreciate the opportunity to hear EPA's ideas as well and to discuss both perspectives. I look forward to our discussion on these provisions in the near future.

SUMMARY

This letter provides ACC's initial views about some of the key aspects of amended section 14 as they relate to confidential chemical identities. In summary:

- The LCSA amendments to section 14 essentially continue the statutory approach to protection of confidential chemical identities from disclosure embodied in the original TSCA.
- Section 14(a) is a reverse-FOIA provision which prohibits EPA from disclosing confidential business information (CBI) exempt from mandatory disclosure under exemption (b)(4) of the Freedom of Information Act (FOIA), except as provided elsewhere in section 14.
- Section 14(b) identifies limited exclusions from section 14(a). These exclusions continue to allow CBI claims for confidential chemical identities, even if contained within health and safety studies that must otherwise be disclosed.
- FOIA mandates disclosure; TSCA does not. To the extent that information excluded by section 14(b) is also exempt from mandatory disclosure under FOIA exemption (b)(4), EPA has discretion to disclose or withhold that information. EPA should continue to



balance the competing interests of public access to the CBI in health and safety studies and protection of trade secrets contained in those studies. Where a structurally descriptive generic name is provided, as is now mandated by section 14(c)(1)(C), disclosure of the specific chemical identity is not necessary. Thus, wherever structurally descriptive generic names are provided, EPA should not disclose confidential chemical identities covered by section 14(b).

- Section 14(g)(4) directs EPA to establish a unique identifier for each specific chemical identity for which it approves a request for protection from disclosure. EPA should not assign unique identifiers in a manner that reveals confidential chemical identities.

DISCUSSION

1. The LSCA Made Few Changes Relating to the Confidential Status of Chemical Identities Claimed as CBI

The amendments to section 14 did not affect the basic issue of whether confidential chemical identities must be protected from disclosure or must be disclosed. Instead, they primarily addressed the processes information submitters will follow when requesting protection from disclosure of CBI, and that EPA will use when evaluating those claims. Nothing in the legislative history of the LCSA suggests a congressional intent to alter the previous provisions as they relate to disclosure or protection of confidential chemical identities in health and safety studies submitted under TSCA.¹

Before the recent amendments, section 14(b) did not apply to CBI in health and safety studies that would reveal process information and that continues to be the case. However, an amendment clarified that among the process information that is excluded from section 14(b) (and which therefore is protected by section 14(a)) is “formulas (including molecular structures) of a chemical substance or mixture.” The term “molecular structures” is a way of referring to chemical identities.² Thus, amended section 14(b) expressly protects confidential chemical identities from disclosure when the identities would reveal process information. This express protection does not imply, however, that confidential chemical identities that would not reveal process information are subject to section 14(b). EPA retains the discretion to protect confidential chemical identities in other circumstances.

In light of the small substantive change to section 14(b), most aspects of the attached 2012 ACC White Paper, “TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure,” (White Paper) remain relevant.³ The White Paper reviews policy reasons why

¹ ACC acknowledges one exception to this point – namely the clear mandate to disclose what had been protected as CBI when CBI protections are withdrawn or cannot be maintained.

² Section 10(b) of FIFRA, which protects trade secrets from disclosure, similarly specifies that “formulas of products” may not be disclosed, even though health and safety studies must otherwise be disclosed. That provision has long been understood as precluding EPA from disclosing the confidential chemical identities of inerts in a pesticide formulation, even if mentioned in a health and safety study.

³ ACC submitted the White Paper to EPA on January 20, 2012, and discussed it with Assistant Administrator Jim Jones and his staff in a meeting on February 14, 2012.

EPA should protect confidential chemical identities from disclosure;⁴ interprets statutory provisions throughout TSCA that protect such identities from disclosure;⁵ shows how the legislative history of section 14(b) supports protection of confidential chemical identities; and reviews EPA's practices throughout its implementation of TSCA to protect those identities.

The White Paper recommends that EPA require up-front substantiation of CBI claims for confidential chemical identities and disclosure of structurally descriptive generic names for such identities. The amendments to section 14 effectively implement both of those recommendations.

2. Section 14(a) Prohibits Disclosure of CBI Not Subject to an Exception

It is helpful to recognize section 14(a) as a reverse-FOIA provision that prohibits disclosure of information exempt from mandatory disclosure under FOIA, except to the extent that other provisions of section 14 (such as section 14(b)) create exceptions to that prohibition. Congress enacted this and other reverse-FOIA provisions because "FOIA is exclusively a disclosure statute" and "does not give the authority to bar disclosure" because "Congress did not design the FOIA exemptions to be mandatory bars to disclosure."⁶ The point of a reverse-FOIA provision is to prohibit disclosure. Section 14(a) has counterparts in other federal regulatory statutes.⁷

Accordingly, section 14(a) establishes the basic approach for deciding whether to protect confidential chemical identities from disclosure. That protection is mandatory except to the extent that an exception applies. This means that the exceptions should be read narrowly.

3. Under Section 14(b), Confidential Chemical Identities in Health and Safety Studies Are Protected from Disclosure

The LCSA made only minor changes to the exceptions in section 14(b) from the protection from disclosure provided by section 14(a). The meaning of those exceptions essentially has not changed.

In 2010, EPA announced its interpretations of the section 14(b) exceptions.⁸ Generally, those interpretations indicated that EPA would not protect from disclosure chemical identities on the public Inventory (unless the identities revealed process or percentage of mixture information). In response, ACC submitted to EPA the attached White Paper disagreeing with certain EPA interpretations and policy changes. In particular, the White Paper maintained that under section 14(b)(1), health and safety effects information in studies submitted under TSCA is not protected from disclosure, but confidential chemical identities (whether or not on the confidential Inventory) in those studies are protected from disclosure.

⁴ One of those policy reasons was protection of trade secrets because of the economic value that they bring to the U.S. That reason was reiterated by the recent enactment of the Defend Trade Secrets Act of 2016, Pub. L. 114-153 (May 11, 2016) only a few weeks before enactment of the LCSA.

⁵ In some cases, the LCSA revised the subsections in which those provisions appear, but most or all remain in TSCA as amended.

⁶ *Chrysler Corp. v. Brown*, 441 U.S. 281, 285, 293-294 (1979).

⁷ E.g., Consumer Product Safety Act § 6(a)(2), 15 U.S.C. § 2055(a)(2).

⁸ 75 Fed. Reg. 3462 (Jan. 21, 2010) (confidential chemical identities submitted under section 8(e)); 75 Fed. Reg. 29754 (May 27, 2010) (confidential chemical identities in health and safety studies).

The legislative history of the LCSA's amendments to section 14(b) apparently referred to this debate:

[The Senate Committee bill] retains virtually verbatim the language of existing section 14(b)(1), relating to the disclosure of confidential information in the context of a health and safety study. The adoption of this provision of existing law does not signal the Committee's intent to agree or disagree with EPA's interpretation of the provision to date. Rather, it reflects the significant debate over the scope and interpretation of that provision, which could not be successfully resolved.⁹

However, Congress did enact new language relating to CBI contained in a health and safety study, new section 14(b)(1), which provides:

MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—
Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

The Senate Committee Report commented on an earlier version of that language, stating:

The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.¹⁰

The House Committee Report made the same point:

Fifth, the legislation clarifies that while health and safety studies about a specific chemical substance or mixture are not eligible for protection as CBI, those studies cannot reveal data that would disclose formulas, including molecular structures, for chemical substances and mixtures whose protection as confidential has been justified to EPA. The Committee expects that redactions or the use of approved generic names or unique identifiers will be employed to meaningfully inform the public without comprising trade secrets.¹¹

This position is similar to that espoused by the EPA General Counsel in 1976, who opined that the 1972 version of FIFRA mandated the disclosure of effects information in health and safety studies submitted under FIFRA, but protected from disclosure "confidential ingredient

⁹ S. Rep. 114-67 (June 18, 2015) at 22, <https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf>.

¹⁰ Id.

¹¹ H.R. Rep. 114-176 (June 23, 2015) at 30, <https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf>.

statements” in those studies.¹² Other environmental statutes also require disclosure of effects information but protect confidential chemical identities from disclosure.¹³

With this clarification in new section 14(b)(1), Congress clearly contemplated that not everything in a health and safety study is to be disclosed if it would otherwise be protected by section 14(a). It strongly suggests that confidential chemical identities otherwise protected by section 14(a) must be protected from disclosure.

In short, section 14 protects confidential chemical identities in health and safety studies submitted under TSCA, even if those identities are on the public TSCA Inventory.

4. Section 14(b) Does Not Mandate Disclosure of Health and Safety Studies

Amended section 14(b)(2) does not mandate disclosure of health and safety studies submitted under TSCA; instead, it provides simply that “Subsection (a) does not prohibit the disclosure of” certain health and safety studies and other specified information. FOIA does not mandate disclosure of such CBI either, due to exemption (b)(4). Because CBI in health and safety studies subject to section 14(b)(2) is neither protected from disclosure nor subject to mandatory disclosure, EPA must exercise its discretion in deciding whether or not to disclose such CBI.

Historically, EPA has exercised that discretion by balancing the competing interests of disclosure and protection against loss of trade secrets. In the context of health and safety studies submitted with PMNs, EPA has concluded that it will not protect confidential chemical identities from disclosure *unless* “[t]he specific chemical identity is not necessary to interpret a health and safety study.”¹⁴ Where the specific chemical identity is unnecessary for that purpose, it will protect the CBI. When adopting this position, EPA explained:

In an attempt to meet both these concerns, EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA...

Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies ...

Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. **Sufficiently specific generic names will tend to**

¹² Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.), quoted in the White Paper at p. 17.

¹³ See the White Paper at pp. 23-26; Resource Conservation and Recovery Act of 1976, Pub. L. 94-580 (Oct. 21, 1976), § 3007(b) (enacted 10 days after TSCA).

¹⁴ 40 C.F.R. § 720.90(c).

support arguments that disclosure of the specific chemical identity is not necessary to understand the study.¹⁵

As amended by the LCSA, section 14(c)(1)(C) now mandates that any claim for protection of confidential chemical identities must include “a structurally descriptive generic name.” With this new requirement, the balancing of interests should always favor protection of the CBI.

5. EPA Should Not Implement the Unique Identifier Provision to Reveal CBI

New section 14(g)(4) directs EPA to assign a unique identifier to any confidential chemical identity which it withholds from disclosure. This identifier must be unique, in contrast to a structurally descriptive generic name, which can apply to multiple chemical substances having a similar molecular structure. The purpose behind this provision is to provide an easy way of identifying all related CBI information that would be disclosed when a claim is withdrawn, denied, or when the criteria for protection are not met. However, the unique identifier must be applied very carefully so as not to inadvertently disclose confidential information. EPA must take care to protect links to company identities and information on commercialization when that information is claimed confidential.

Where the confidential chemical identity is already on the confidential Inventory, the accession number could serve as the unique identifier. There are no accession numbers for chemicals that are not on the Inventory, however, so accession numbers must only be one source among others for unique identifiers.

For example, many R&D chemicals are not on the TSCA Inventory. A PMN submitter must submit all health and safety studies on the PMN substance as part of the PMN, at which time the PMN substance does not have an accession number (and EPA would assign an accession number only if subsequent to the end of the PMN review period the PMN submitter were to submit a notice of commencement). In addition, chemicals being evaluated for their potential to be used as pesticides (subject to TSCA prior to application of FIFRA¹⁶) are typically not on the Inventory, and yet they may be the subject of submissions under section 8(e). If those pesticide candidates are successful, they would become subject to FIFRA and would never receive an accession number. For these chemicals, EPA would either have to assign a unique identifier other than an accession number, or delay assigning a unique identifier until such time, if ever, that it does assign an accession number.

¹⁵ 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added). This resolution parallels the legislative history of section 5(d)(2), which directs EPA to identify PMN chemicals in Federal Register notices “by generic class” unless a more specific identification is required in the public interest. The Senate Report for an early TSCA bill with a provision which became section 5(d)(2) in a later bill explained that such a generic name, “coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results.” S. Rep. No. 97-283 at 20 (1972). In other words, Congress contemplated that having a structurally descriptive generic name would enable the public to understand a study without the need to disclose confidential chemical identities revealed in the studies.

¹⁶ See 40 C.F.R. § 720.36(g).

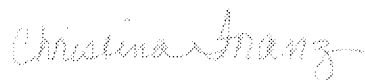
In addition, as discussed in section 3 of this letter, a confidential chemical identity may be on the public Inventory. These chemicals will not have accession numbers either. Thus, EPA will have to derive unique identifiers for these chemicals as well.

Where EPA has agreed to protect from disclosure a confidential chemical identity that is on the public Inventory, it should not use the unique identifier to reveal that identity by applying it to public information that specifically identifies that chemical. For example, if it is a trade secret that chemical X (which is on the public Inventory) is in a formulated product that is the subject of study submitted to EPA under TSCA, and EPA has agreed to keep the identity of chemical X confidential with respect to that study, EPA should not apply the unique identifier to other public information that gives the specific chemical identity of chemical X. That would reveal the very information that EPA had agreed to keep confidential.

CONCLUSION

I look forward to discussing the paper with you and your staff.

Sincerely,



Christina Franz
Senior Director, Regulatory & Technical Affairs

Enclosure: ACC White Paper, "TSCA Protects Confidential Identities in Health and Safety Studies From Disclosure" (Feb. 21, 2012)

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CHEMICALS**CONFIDENTIAL BUSINESS INFORMATION**

Citing Section 14(b) of the Toxic Substances Control Act, the Environmental Protection Agency has recently called for the disclosure of chemical identities in health and safety studies submitted under TSCA, notwithstanding objections by the study submitters that the chemical identities are trade secrets or confidential commercial information. EPA has developed a policy against confidential business information protection for chemical identities in or underlying such studies. In this article, the authors say EPA should reconsider that CBI disclosure policy for both policy and legal reasons, and take specific steps to protect confidential chemical identities where appropriate. Under TSCA, EPA must balance the interest in disclosure against the interest in protecting trade secret and confidential chemical identities. It may do so by protecting that information while also providing the public with the information it needs to evaluate those studies, such as through a requirement for structurally descriptive generic names.

**TSCA Protects Confidential Chemical Identities
In Health and Safety Studies From Disclosure**

By MARK N. DUVALL AND CHRISTINA FRANZ

There are strong policy reasons why EPA should reconsider its stance against CBI protection for chemical identities in health and safety studies. Trade secrets are crucial to U.S. leadership in innovation in a global economy, but the CBI disclosure policy

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This article does not represent the opinions of BNA, which welcomes other points of view.

may erode that leadership by reducing the protection for trade secrets. In the chemical industry, trade secret chemical identities are among the most valuable intellectual property, yet they often cannot be patented. The composition of formulations can be particularly valuable, especially for small businesses. Under the CBI disclosure policy, EPA would reveal those chemical identities when they are the subject of a health and safety study submitted under TSCA, notwithstanding CBI claims. This may have the effect of discouraging innovation and the jobs and greener chemicals that result from innovation, and driving jobs outside the United States.

The CBI disclosure policy reflects EPA's legal perspective that Section 14(b) *requires* disclosure of trade secret or confidential chemical identities in most studies submitted under TSCA. That perspective is flawed. The CBI disclosure policy runs counter to the text and

legislative history of TSCA, as well to nearly 30 years of EPA policy and regulation. This paper establishes that in Section 14 and the rest of TSCA, Congress intended for EPA to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA, while also providing the public with the information it needs to evaluate those studies.

The congressional intention to protect trade secret or confidential chemical identities is reflected in the text of TSCA itself. Read as a whole, TSCA shows consistent concern for the protection of chemical identities that are trade secrets or confidential commercial information:

- Section 14(a) provides broad protection for trade secret or confidential commercial information. Section 14(b) cuts back on that protection for health and safety studies, but it requires health and environmental information, such as effects information, to be available for disclosure, not trade secret or confidential commercial information in those studies. Section 14(a) protects any trade secret or confidential commercial information in those studies other than health and environmental information.
- Both Sections 5(b)(3) and 5(d)(2) mandate public disclosure of data from health and safety studies submitted under Section 5, subject to protection for trade secret or confidential chemical identities and other information in those studies under Section 14. Section 5(d)(2) specifically endorses disclosure of generic names instead of confidential identities except where “required in the public interest.”
- Section 4(d) similarly mandates public disclosure of data from health and safety studies submitted under Section 4, subject to protection for trade secret or confidential chemical identities and other trade secret information in those studies under section 14.
- Section 8(a) authorizes EPA to require reporting of chemical identities and other information that is typically confidential without even mentioning Section 14, indicating an expectation that Section 14(a) protects such information when it is trade secret or confidential.
- Section 14(b) excludes trade secret or confidential chemical identities that, if disclosed, would result in disclosure of process information.
- Section 14(b) also excludes studies on R&D chemicals, for which the public interest in disclosure of trade secret or confidential commercial information is generally limited and the competitive interest in nondisclosure of such information is generally high.

This intention to protect trade secret or confidential chemical identities while disclosing health and safety studies is also manifest in the legislative history of TSCA. When Congress was considering TSCA, lawmakers recognized that the 1972 amendments to the Federal Fungicide, Insecticide, and Rodenticide Act, which also required the disclosure of health and safety studies, had raised a question of whether a study could be claimed as a whole to be a trade secret or confiden-

tial commercial information and thereby be protected from disclosure. EPA took the position that studies as a whole are not trade secrets or confidential commercial information.

With section 14(b), Congress intended to incorporate that position into TSCA. However, in the FIFRA debate, EPA carefully differentiated between studies as whole and chemical identities in or underlying those studies. EPA concluded that the trade secret or confidential identities in studies submitted under FIFRA are protected from disclosure. Stakeholders in the TSCA hearings similarly advocated for disclosure of studies, but recognized the need for continued protection of trade secret or confidential chemical identities. With Section 14 of TSCA, Congress adopted EPA’s viewpoint both that studies as a whole are not protected from disclosure, and that trade secret or confidential commercial information in or underlying them should be protected from disclosure.

TSCA is the second of six statutes enacted by Congress between 1972 and 1986 related to public disclosure of health and environmental information about chemicals. In all five of the other statutes, disclosure of health and environmental information is required, but trade secret or confidential chemical identities are protected from disclosure. TSCA is not an exception, but rather should be recognized to be part of the same congressional approach: making health and environmental effects information public while protecting competitively sensitive information such as chemical identities.

EPA has long recognized that it has authority under Section 14 to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA. In multiple rulemakings under Section 5, it explicitly balanced the interest in disclosure of studies against the interest in protecting trade secret or confidential chemical identities in those studies by requiring disclosure except where disclosure is unnecessary to interpret the studies, such as by the provision of structurally descriptive generic names. This longstanding legal interpretation by EPA is consistent with the text and legislative history of TSCA.

EPA should take several steps to balance transparency with protection of competitively sensitive information:

- Currently, EPA’s regulations and guidance disallow confidentiality claims for chemical identities in or underlying studies, other than to a limited extent in its premanufacture notice (PMN) and microbial commercial activity notice (MCAN) regulations. EPA should revise those regulations and guidance to allow such claims in appropriate circumstances. It should not proceed with its planned initiative to delete those provisions in its PMN and MCAN regulations.
- To address the need for public understanding of health and safety studies, EPA should consider requiring that structurally descriptive generic names be provided in lieu of trade secret or confidential chemical identities for all studies submitted under TSCA. Generic names can provide important information to the public while still protecting competitively sensitive information that is important for innovation. EPA should also consider requiring up-front substantiation of CBI claims for chemical identities in studies.

- EPA should work with industry and nongovernmental organizations to improve the process for determining appropriate generic names, both for the identities of chemical substances in studies and for names of PMN substances. The current process is unnecessarily resource-intensive. Industry representatives would volunteer to work with EPA and NGOs to streamline and otherwise improve the process.
- EPA should allow CBI claims for confidential identities of chemical substances in or underlying health and safety studies where appropriate. With structurally descriptive generic names, an improved process for determining generic names, and an up-front substantiation requirement, the balance between transparency and protection of competitively sensitive information would be shifted to allow the disclosure of generic names rather than specific chemical identities where appropriate.
- EPA should not require disclosure of the components of R&D mixtures that are the subject of studies. Section 14(b) does not apply to mixtures that have not been offered for commercial distribution, such as R&D mixtures. Accordingly, EPA should protect confidential identities of components of R&D mixtures.

I. Policy Reasons Why EPA Should Reconsider Its Interpretation of Section 14

EPA has a policy of requiring disclosure of confidential chemical identities in or underlying health and safety studies submitted under TSCA. EPA should reconsider that CBI disclosure policy. It is based on a flawed interpretation of Section 14 and may have serious adverse impacts on innovation and on small business. It may help drive chemical industry jobs overseas.

EPA must consider these impacts. In Section 2(c) of TSCA, Congress expressed its intent that EPA "shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action" taken under TSCA. The CBI disclosure policy is neither reasonable nor prudent, and it may be having adverse economic and social impacts. Further, in Section 2(b)(3), Congress found that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." The CBI disclosure policy is such an unnecessary economic barrier to innovation.

Trade secret protection is crucial to U.S. competitiveness. According to the National Science Foundation's National Science Board, intellectual property in the form of trade secrets is a critical factor as the United States competes in a global marketplace:

In most broad aspects of S&T [science and technology] activities, the United States continues to maintain a position of leadership but has experienced a gradual erosion of its position in many specific areas

The United States runs a surplus with the rest of the world in trade of intangible assets, including patent licensing fees and use of trade secrets An important component of the surplus in U.S. intangible as-

sets is generated by industrial processes (\$19 billion), which include licensing fees for patents and use of trade secrets. U.S. exports in this category were \$37 billion in 2007.¹

The United States needs to protect its leadership in scientific and technological innovation. In the chemical industry, innovation often depends upon trade secret protection for trade secret or confidential chemical identities.

Trade secret protection also serves important public policy goals. As the Supreme Court has noted:

Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor by contracting with a company large enough to develop and exploit it. Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.²

More particularly, confidential chemical identities in health and safety studies have recognized economic value, as a government report found:

Further, specific identification of a product in a health and safety study may inform competitors that a product has commercial value or that it is used in a particular manufacturing process. This concern is particularly applicable to catalysts and intermediates that may not be detectable in the commercial product.

Although the sensitivity of releasing confidential data is greatest at the beginning of a product's commercial life cycle, release of such data about an existing product may have some of the same economic consequences as disclosure of confidential data regarding a new product.³

The legislative history of TSCA includes the following plea for the recognition of the importance of trade secret chemical identities to their owners:

Particularly in the chemical industry, the precise identification of ingredients . . . may involve the results of research and development expenditures of considerable magnitude. Rights in trade secrets can be among the most valuable property rights owned by a company. Buildings and equipment can be replaced at predictable costs, but secrets once lost to

¹ National Science Board, *Science and Engineering Indicators 2010* (2010), <http://www.nsf.gov/statistics/seind10/pdfstart.htm> at O-3, 6-5.

² *Kewanee v. Bicron Corp.*, 416 U.S. 470, 492 (1974).

³ "Toxic Chemicals and Public Protection: A Report to the President by the Toxic Substances Strategy Committee" (1980) at 48. The Committee consisted of representatives from the Council on Environmental Quality, eight executive branch departments, and other agencies.

competitors are gone forever, and with them the incalculable advantages their owners earned.⁴

New chemical substances and new mixtures of existing chemical substances usually take millions of dollars to develop. Public disclosure of their chemical identities would make the fruits of those investments readily available to others who do not have to make similar investments. EPA has acknowledged that “there is no doubt that the fact that certain substances are manufactured or processed for commercial purposes would be confidential under traditional trade secrets law and case law under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b) (4)).”⁵ Yet information that is public knowledge cannot be a trade secret.⁶

Forced disclosure of trade secret or confidential chemical identities under EPA’s interpretation of Section 14 means that innovators may have less incentive to invest the resources necessary to develop the new chemicals and mixtures that could promote the health and well-being of Americans and the environment. Increasingly, “greener” chemicals are being developed to replace those with greater possible risk to health or the environment. Without the potential for economic returns on investment made possible through CBI protection, those greener chemicals may never be introduced.

Lack of CBI protection may also drive innovation and jobs overseas. Companies may seek to manufacture chemicals in other countries where the confidentiality of their chemical identities is protected from disclosure.

Many businesses, and particularly small businesses, often innovate by combining existing chemical substances in new ways. Such combinations are typically not eligible for patent protection. Their combination creates considerable value, however, but only if protected from disclosure. EPA’s CBI disclosure policy applies to the components of mixtures, and thus may inhibit innovation in development of new and improved formulations.

In light of these considerations, EPA should critically review its CBI disclosure policy. With some changes to that policy, it can still achieve its transparency goals without disclosing trade secret or confidential chemical identities. For example:

- Where chemical identities in or underlying a study are to be withheld, EPA can require the development of structurally descriptive chemical names that will give context to the studies for the public, thus enabling both an evaluation of the studies themselves and searches of the toxicological literature for related compounds.⁷

⁴ Statement by Dow Chemical Co., “Toxic Substances Control Legislation—1973: Hearings Before the Subcommittee on Commerce and Finance of the House Committee on Interstate and Foreign Commerce,” 93d Cong., 1st Sess. (1973) at 355-56. Congressional materials cited in this paper are available in the LexisNexis Congressional Hearings Digital Collection.

⁵ 42 Fed. Reg. 64572, 64590 (Dec. 23, 1977) (comment 93).

⁶ *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) (citing the Restatement of Torts).

⁷ EPA already requires development of generic names for chemical identities claimed as CBI in submissions under Section 5 (40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3)). Its former inventory regulations required submission of a generic name with a CBI claim for chemical identity. 40 C.F.R. § 710.7(e)(2)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977). EPA also requires submission of a generic name un-

- EPA can require up-front substantiation of claims that chemical identities in or underlying studies are trade secrets or confidential commercial information, thus discouraging inappropriate CBI claims.⁸

- EPA can require reassertion and resubstantiation of previous CBI claims so as to remove confidentiality protection for stale CBI claims, an idea already in development.⁹

Moreover, as explained in the following sections, EPA’s legal conclusion that it must disclose trade secret or confidential chemical identities in or underlying health and safety studies is simply incorrect. The information provided below, the legislative history in particular, may not have been considered fully by EPA in formulating its CBI disclosure policy.

II. Background on Section 14

With some exceptions, Section 14(a) broadly prohibits EPA from disclosing information that is exempt from mandatory disclosure to the public under exemption (b)(4) of the Freedom of Information Act (FOIA), for “trade secrets and commercial or financial information obtained from a person and privileged or confidential.”¹⁰ Trade secret or confidential chemical identities are included within the protections of Section 14(a).

Section 14(b) limits the scope of Section 14(a) by providing that it “does not prohibit the disclosure of — (A) any health and safety study which is submitted under this Act” Section 14(b) is itself limited by several qualifications. Not all studies submitted under TSCA are covered, only those with respect to:

- (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
- (ii) any chemical substance or mixture for which testing is required under Section 4 or for which notification is required under Section 5

In addition, Section 14(b) contains the following exclusion from its coverage:

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

der the Emergency Planning and Community Right-to-Know Act of 1986 (40 C.F.R. § 370.64(a)).

⁸ EPA already requires up-front substantiation for CBI claims for chemical identities submitted under Section 5 (40 C.F.R. §§ 720.85(b)(3)(iv), 721.1(c), 725.94), Section 4 (40 C.F.R. § 790.7(c)), and Section 8(a)’s Chemical Data Reporting Rule (40 C.F.R. § 711.30(b)(1)).

⁹ According to the Spring 2011 Regulatory Agenda, RIN 2070-AJ90, “EPA is considering establishing regulations relating to claims for confidential business information (CBI) submitted under the Toxic Substances Control Act (TSCA) that would require the periodic reassertion and resubstantiation of such claims. Confidentiality claims which are not reasserted and resubstantiated would expire. EPA expects this action would increase transparency and availability of public health and environmental effects information on chemicals in commerce.”

¹⁰ 5 U.S.C. § 552(b)(4).

EPA has promulgated regulations under sections 5 and 8(d), in connection with definitions of the term “health and safety study,” saying that chemical identity is always part of, or underlying data to, a health and safety study.¹¹ If the identity of the chemical being tested is not disclosed in the study itself (e.g., because a trade name is used instead), then the specific chemical identity is reasonably considered to be underlying data for the study. This conclusion, however, does not answer the question of whether the identity must be disclosed to the public when it is a trade secret or confidential commercial information.

Recently, EPA has taken the position that Section 14(b) means that a trade secret chemical identity must be disclosed whenever it is part of, or underlying data for, a health and safety study submitted under TSCA. In May 2010, EPA declared:

EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted. Congress did not specifically exempt chemical identities from TSCA section 14(b), and EPA believes that interpreting TSCA section 14(b) in such a manner would be inconsistent with the intent of Congress in enacting that provision.¹²

This interpretation of the statute is not correct. Congress intended for EPA to protect chemical identities in submitted health and safety studies while also providing the public with the health and environmental information it needs to evaluate those studies. In other words, EPA must balance the competing interests, as it has done for nearly 30 years.

III. The Text of TSCA Shows Intent to Protect Trade Secret or Confidential Chemical Identities in Submitted Health and Safety Studies

The text of TSCA itself establishes that Congress intended for EPA to balance the interest in disclosure of health and safety studies against the competing interest in nondisclosure of trade secret or confidential competitive information in or underlying those studies. The studies may be made public, but EPA must protect such information in those studies.

A. Section 14(a) Protects Trade Secret or Confidential Commercial Information in or Underlying Studies

Section 14(a) provides broad protection for trade secret or confidential commercial information submitted to EPA. It states in part:

Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator . . . under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be dis-

closed by the Administrator [with certain enumerated exceptions¹³].

That protection extends to trade secret or confidential chemical identities in appropriate cases, as demonstrated by court decisions interpreting FOIA exemption (b)(4).¹⁴ As the EPA General Counsel has found with respect to FIFRA:

Moreover, confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely. If inquiry shows that the information is in fact confidential in the submitter's hands, and that its disclosure would be likely to cause substantial harm to the submitter's competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.¹⁵

Congress emphasized the importance of protecting information subject to Section 14(a) from disclosure. Section 14(d) authorizes criminal penalties for wrongful disclosure, and Section 14(a)(3) limits EPA's discretion to disclose protected information outside of specified contexts to where EPA determines that disclosure “is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.”

Were it not for Section 14(b), there would be no question that trade secret or confidential chemical identities in or underlying health and safety studies submitted under TSCA would be protected from disclosure. Accordingly, the real question is whether anything in Section 14(b) undercuts that protection of trade secret or confidential chemical identities.

One obvious point to make is that section 14(b) nowhere refers to chemical identities; instead, it refers to health and safety studies. Section 14(b) provides that Section 14(a) “does not prohibit the disclosure of” studies submitted under TSCA, but it specifically does not require that otherwise protected information in or underlying those studies be made public. By explicitly prohibiting disclosure of process and portion of mixture in-

¹³ One of the exceptions is use in a proceeding under TSCA, but, in language unusual for an environmental statute, Section 14(a)(4) provides that disclosure in a proceeding “shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding.” Thus, Congress chose to emphasize the importance of preserving confidentiality even in the case of a limited exception to Section 14(a).

¹⁴ See, e.g., *Appleton v. FDA*, 451 F. Supp. 2d 129, 142 & n.7 (D.D.C. 2006) (drug chemical composition); *Kennedy v. DHS*, No. 03-6076, 2004 WL 2285058, at *7 (W.D.N.Y. Oct. 8, 2004) (protecting names and coding of inks) *Center for Auto Safety v. NHTSA*, 93 F. Supp. 2d 1, 40-41 (D.D.C. 2000) (identity of inflator gas used for air bags); *Northwest Coalition for Alternatives to Pesticides v. Browner*, 941 F. Supp. 197 (D.D.C. 1996) (reviewing individual chemical identities under FOIA exemption 4); *Citizens Comm'n on Human Rights v. FDA*, No. 92-5313, 1993 WL 1610471, at *7 (C.D. Cal. May 10, 1993) (information about how a pioneer drug product is formulated and chemically composed), *aff'd in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir. 1995).

¹⁵ Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.-A.G.C.) (emphasis added).

¹¹ 40 C.F.R. § 716.3 (“Chemical identity is part of, or underlying data to, a health and safety study.”); § 720.3(k) (“Chemical identity is always part of a health and safety study.”); § 725.3 (“Microorganism identity is always part of a health and safety study of a microorganism.”).

¹² 75 Fed. Reg. 29754, 29756 (May 27, 2010).

formation, Section 14(b) clearly contemplates that EPA must protect from disclosure at least some trade secret or confidential information in or underlying submitted studies.

The exclusions from Section 14(b) are not exhaustive. For example, EPA has declared in its Section 8(d) rules that Section 14(b) does not extend, in appropriate cases, to information such as “company name or address, financial statistics, and product codes used by a company, which is contained in a study.”¹⁶ Section 14(b) has no explicit exemption for such information. However, as confidential financial statistics and product codes are both kinds of information protected by Section 14(a) and are not themselves health or environmental effects information, Section 14(b) should not be read to preclude the application of Section 14(a) to such information. More generally, Section 14(a) continues to apply to other trade secret or confidential commercial information in or underlying those studies that is not health or environmental effects information, including confidential chemical identities.

B. Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 5

One situation in which Section 14(b) applies is where studies have been submitted under Section 5, in connection with either a premanufacture notice (PMN) or a significant new use notice (SNUN). In some situations, the submitter of a PMN or SNUN must submit health and safety data to EPA. Section 5(b)(3) provides that such data “shall be available, **subject to section 14**, for examination by interested persons.” (Emphasis added.) The reference to Section 14 reflects congressional concern for confidential competitive information; otherwise, Section 5(b)(3) could simply require disclosure.

In all situations, Section 5(d)(1) requires the submitter of a PMN or SNUN to submit “any test data in the possession or control” of the submitter. Section 5(d)(2) requires public release (in the form of a *Federal Register* notice) of a summary of that test data and any data submitted under Section 5(b) or 4:

Subject to section 14 . . ., the Administrator shall publish in the *Federal Register* a notice which—

- (A) identifies the chemical substance for which notice or data has been received;
- (B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substances and any data which was developed pursuant to subsection (b) or a rule under section 4.

(Emphasis added.) Again, Congress felt the need to invoke Section 14 so as to protect competitively sensitive information. In addition, Section 5(d)(2) specifically addresses chemical identities:

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

Thus, trade secret or confidential chemical identities in health and safety studies submitted under Section 5 are to be protected by use of generic names unless, in balancing the respective interests at stake, EPA determines that disclosure is necessary.

A provision requiring disclosure of chemical identities of PMN chemicals in *Federal Register* notices appeared in the 1972 TSCA bill.¹⁷ The accompanying Senate report expressed support for the use of generic names in lieu of specific chemical identities in those *Federal Register* notices, as now appears in Section 5(d)(2):

It is anticipated that a limited amount of data will be published in the *Federal Register*, since a disclosure of the identity of the chemical substance and intended uses prior to its commercial production would, in many cases, result in the disclosure of trade secrets that would be protected by section 115. However . . . , it may be possible to identify a chemical as a member of a family of chemical substances without disclosing trade secret information. This information, coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results.¹⁸

Section 5(d)(2) may be seen as a response to an industry letter calling for complete protection of chemical identity and use information in *Federal Register* notices:

Member firms have continually objected to the release of unnecessary information via *Federal Register* publication. Publication of such information has the very definite effect of discouraging product innovation and the release of new and valuable chemical specialty products. We suggest, therefore, that any requirement for *Federal Register* publication in any toxic substances legislation exclude information pertaining to proposed uses and composition because

¹⁶ “Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company [in a study]. This information will not be subject to the disclosure requirements of section 14(b) of TSCA.” 40 C.F.R. § 716.55(a)(4). When adopting the predecessor provision in 1982, EPA asserted that it was justified by exemption 6 of FOIA, for “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 47 Fed. 38780, 38788 (Sept. 2, 1982). In adopting the current provision, EPA wisely no longer relied on exemption 6, which the Supreme Court has held applies only to individuals, not to companies. See, e.g., *FCC v. AT&T, Inc.*, No 09-1279 (S. Ct. Mar. 1, 2011) (interpreting exemption 7(C) consistently with exemption 6 to apply only to the privacy interests of individuals). Thus, the provision relies on exemption 4, the same exemption that applies to confidential chemical identities.

¹⁷ S. 1478 (1972), § 104(a), S. Rep. No. 92-783 at 3 (1972) (“Subject to section 115 of this title [captioned “Confidentiality”], the Administrator shall promptly publish in the Federal Register the identity of such chemical substance, the uses intended, and a statement of availability of test data.”).

¹⁸ S. Rep. No. 92-783 at 19-20 (1972) (emphasis added).

such data constitutes confidential commercial and trade secret information.¹⁹

Congress did not categorically exclude composition and use information from Federal Register notice requirements, as requested. In Section 5(d)(2) it did, however, protect composition information through the use of generic names except where EPA's balancing of interests indicates otherwise.

It would make no sense for EPA to be required by section 14(b) to disclose those same trade secret identities protected by Section 5(d)(2) when it makes the studies themselves available for disclosure. Thus, while Section 14(b) means that public disclosure of studies submitted in connection with a PMN or SNUR is not prohibited, TSCA protects any trade secret or confidential chemical identities in or underlying those studies from disclosure.

C. Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 4

A second situation in which Section 14(b) applies is where a chemical substance or mixture is the subject of testing requirements under Section 4.²⁰ As with studies submitted under Section 5, this means that the resulting studies themselves are not prohibited from disclosure. However, the trade secret or confidential identity of the tested chemical substance or mixture is subject to protection from disclosure under Section 14(a). This may be seen in Section 4(d), which provides (emphasis added):

Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice of the receipt of such data in the *Federal Register* within 15 days of its receipt. **Subject to section 14**, each such notice shall (1) identify the chemical substance or mixture for which data has been received **Except as otherwise provided by section 14**, such data shall be made available by the Administrator for examination by any person.

That Section 4(d) was intended to protect trade secret or confidential identities from disclosure is apparent from the corresponding provision of a 1975 House bill, H.R. 7664, which included at the end the following additional sentence not included in the final version of TSCA:

Notice under this subsection shall identify the chemical substance by generic class unless the Administra-

¹⁹ Letter submitted by the Chemical Specialty Manufacturers Association, "Toxic Substances Control Act: Hearings Before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce," 94th Cong., 1st Sess. (1975) (1975 House Hearings) at 450.

²⁰ It is unlikely that health and safety studies submitted under Section 4 would involve confidentiality claims for chemical identities. The point here, however, is that Congress anticipated that in some cases there could be a need for confidentiality in Section 4 submissions as well as Section 5 and other submissions under TSCA.

tor determines that more specific identification is required in the public interest.²¹

This is virtually the same language that appears in Section 5(d)(2). Congress ultimately decided not to require disclosure of generic names in the *Federal Register* notice for reports on studies submitted under Section 4, as it did with Section 5, but it clearly intended for EPA to balance the competing interests in making disclosure decisions for studies submitted under Section 4, including with respect to trade secret or confidential chemical identities. Thus, Section 4(d) protects such chemical identities in the *Federal Register* notice announcing receipt of studies submitted under Section 4.

It would make no sense for EPA to be required by Section 14(b) to disclose those same trade secret identities when it makes the studies themselves available for disclosure. Accordingly, Section 14(b) does not mandate disclosure of trade secret chemical identities in studies submitted under Section 4.

D. Section 8(a) Illustrates How Section 14 Protects Chemical Identities

Under Section 8(a), EPA may require manufacturers and processors to report chemical identity information. It specifically mentions "the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required." It restricts EPA's ability to require reporting of "changes in the proportions of the components of a mixture" except in defined circumstances.

Such detailed chemical information is subject to reporting to EPA; but, key to this discussion, it is protected from disclosure to the public. This information is clearly covered by Section 14(a). In the Inventory Update Reporting (IUR) rule, now the Chemical Data Reporting (CDR) rule, EPA has allowed CBI claims under Section 14(a) for such information.²²

With Section 8(a), Congress again recognized that chemical identity information should be protected from disclosure when it is trade secret or confidential. In contrast, Section 14(b) is limited to health and safety studies themselves, not to trade secret or confidential information in or underlying them, such as chemical identities.

E. Protection of Trade Secret or Confidential Chemical Identities in Studies Where Disclosure Would Reveal Process Information

Section 14(b) does not apply to process information, even when that information is in the form of a trade secret or confidential chemical identity related to a study submitted under TSCA:

This paragraph does not authorize the release of any data which discloses process used in the manufacturing or processing of a chemical substance or mixture

²¹ H.R. 7664 § 4(f), 1975 House Hearings at 42. The same language appeared in the 1973 House bill, H.R. 5356, § 4(f), H.R. Rep. No. 93-360 at 4 (1973).

²² EPA has limited CBI claims for chemical identities to those on the confidential portion of the TSCA Inventory, but it has allowed CBI claims for the connection of the manufacturer to the chemical where the chemical identity is not protected from disclosure. 40 C.F.R. § 710.58(b), now 40 C.F.R. § 711.30(b).

EPA has acknowledged that some chemical identities can reveal process information. Its May 2010 policy statement identified polymers and UVCB chemicals as examples of such chemical identities.²³ This is another way in which TSCA protects trade secret or confidential chemical identities in submitted studies.

F. Protection of Trade Secret or Confidential Chemical Identities in Studies on R&D Chemicals and Mixtures

TSCA protects trade secret or confidential identities in studies on R&D chemicals and mixtures by exempting such studies from the provisions of Section 14(b) altogether.

Section 14(b) applies to a health and safety study submitted under TSCA that relates to “any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution.” The key phrase “offered for commercial distribution” excludes studies of R&D chemicals and R&D mixtures. It has a different meaning than the phrase “for commercial purposes,” which EPA has interpreted to include R&D.²⁴

EPA has noted that “Congress, accordingly, seemed to recognize the importance of confidentiality prior to manufacture of a chemical for commercial purposes.”²⁵ More recently, EPA has acknowledged this exclusion for studies of R&D chemical substances in its January 2010 policy statement regarding CBI claims for studies submitted under Section 8(e), many of which relate to R&D chemical substances. That policy statement is limited to studies on chemical substances on the public inventory, i.e., which are no longer R&D.²⁶

This R&D exclusion also applies to mixtures which are themselves the subject of R&D, since Section 14(b) refers to “any chemical substance or mixture which . . . has been offered for commercial distribution” (emphasis added). For example, a processor may be conducting R&D on a mixture of existing chemicals. A submitted study on such an R&D mixture would be excluded from Section 14(b), even if its components were entirely on the inventory. The mixture itself must have been offered for commercial distribution for Section 14(b) to apply to submitted studies on the mixture.²⁷

G. Implications for Other Studies Submitted Under TSCA

Some studies submitted to EPA under TSCA are not submitted under either Section 4 or 5, nor do the identities of the chemicals tested reveal process information, nor do the studies concern R&D chemical substances or mixtures. But the concern expressed throughout TSCA for balancing the interest in disclosure of health and safety studies with the interest in nondisclosure of competitively sensitive information in

or underlying those studies is implicit in Section 14 with respect to these other studies as well.²⁸

Section 14(a) protects from disclosure trade secret or confidential commercial information, such as confidential chemical identities. Section 14(b) provides an exception for health and safety studies, but not for trade secret or confidential commercial information contained in those studies. As discussed above, Congress repeatedly distinguished trade secret or confidential commercial information in or underlying those studies from the studies themselves. Accordingly, while Section 14(b) does not prohibit the disclosure of many studies submitted under TSCA, EPA must still balance the competing interests with respect to competitively sensitive information in or underlying such studies. This conclusion finds additional support in the legislative history of Section 14, discussed below.

IV. The Legislative History Demonstrates That Congress Wanted EPA to Protect Trade Secret or Confidential Chemical Identities When Disclosing Health and Safety Studies

Several TSCA bills were introduced from 1971 to 1976, and all had provisions protecting trade secrets, counterparts to what became Section 14(a). A counterpart to Section 14(b) did not appear until the 1976 House bill, however. Section 14(b) was added to resolve for TSCA an issue that for FIFRA was then under active debate, and which came to the forefront in 1975: whether health and safety data submitted to EPA qualified as trade secrets or confidential commercial information. That issue did not relate to proprietary data in studies, such as trade secret or confidential chemical identities, which under FIFRA were protected.

Accordingly, to understand Section 14(b) properly, it is important to review the history of the debate on confidentiality of health and safety studies under FIFRA that led to section 14(b).²⁹ That history is summarized below, followed by additional TSCA legislative history that refers to this FIFRA debate.

A. 1972 FIFRA Amendments

In 1972, Congress extensively revised FIFRA with enactment of the Federal Environmental Pesticide Control Act of 1972 (FEPCA).³⁰ Among many other changes to FIFRA, FEPCA required public disclosure of studies submitted in connection with applications:

Except as provided by subsection (c) (1) (D) of this section and section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such

²³ 75 Fed. Reg. 29754, 29756 (May 27, 2010).

²⁴ See 40 C.F.R. § 720.3(r)(1)(ii) (defining the term “manufacture or import for commercial purposes” to include R&D); 44 Fed. Reg. 17673-74 (Mar. 23, 1979); *Dow Chemical Co. v. EPA*, 605 F.2d 673, 689 (3d Cir. 1979).

²⁵ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).

²⁶ 75 Fed. Reg. 3462 (Jan. 21, 2010).

²⁷ Accordingly, EPA should deny FOIA requests for the release of chemical identities of mixtures that are the subject of submitted health and safety studies where the mixture itself is not, on the date of proposed disclosure, offered for commercial distribution.

²⁸ To resolve questions arising from the text of a statute, it is well established that legislative intent must be ascertained by looking to the entire statute, read comprehensively as a whole. See, e.g., *Samantar v. Yousuf*, 130 S. Ct. 2278, 2289 (2010) (“[w]e do not . . . construe statutory phrases in isolation; we read statutes as a whole.”) (citation omitted).

²⁹ See, e.g., *National Treas. Employees Union v. Federal Labor Relations Auth.*, 691 F.2d 553, 559 (D.C. Cir. 1982) (“[T]he intent of Congress is paramount, and this intent may appropriately be ascertained from relevant legislative history.”).

³⁰ Pub. L. 92-516 (1972).

other scientific information as he deems relevant to his decision.³¹

While FEPCA called for disclosure of studies, it also protected trade secret or confidential information in or underlying those studies. FIFRA § 10(b) protected trade secrets and confidential information from disclosure. It specifically included, “formulas of products,” i.e., chemical identities and their percentages, within this protection from public disclosure:

Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, **information relating to formulas of products** acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.³²

The exception beginning “when necessary to carry out the provisions of this Act” has its counterpart in Section 14(a) of TSCA, which enumerates four exceptions to protection of CBI related to administration of that act, including disclosure to other federal agencies and in proceedings. Such exceptions are common in statutory guarantees of CBI protection. The exception is not a broad license for EPA to ignore the mandate to protect CBI, but rather a prudential limitation on the extent of protection.

Other aspects of FEPCA also protected confidential identities of inert ingredients from disclosure. Active ingredients and their percentage in formulated products had to appear on the pesticide label, but confidential inert ingredients only had to be reported on the label as a total percentage.³³ FIFRA § 12(a)(2)(D) made it unlawful for any person to reveal “any information acquired by authority of this Act which is confidential under this Act,” and FIFRA § 14(b) made disclosure of “formulas” in some cases a criminal act.

In addition, FIFRA § 3(c)(1)(D) provided an opportunity for data compensation for submitters of studies relied on by EPA in reviewing the application of a second applicant.

A Senate report on the FEPCA legislation commented that disclosure of health and safety studies without disclosure of trade secret identity information would serve the public need for information about the effects of pesticides under review by EPA: “Merely disclosing test results without identifying the pesticide will enable toxicologists and other scientists to evaluate the results that are claimed.”³⁴

cologists and other scientists to evaluate the results that are claimed.”³⁴

B. Debate About Disclosure of Health and Safety Studies Under FIFRA

An issue arose under FEPCA about whether the health and safety studies submitted by applicants and registrants were also covered by FIFRA § 10(b). That issue had immediate relevance to pesticide applicants and registrants, since FIFRA § 3(c)(1)(D)—which allowed EPA to use a previous applicant’s studies in assessing the registration application of a second applicant, subject to data compensation—only applied if “such data is not protected from disclosure by section 10(b).” In other words, if those studies qualified as trade secrets, EPA could neither use them for registering competitive pesticides nor disclose them publicly.

EPA took the position that it could use previously submitted studies for reviewing applications by other companies and could disclose health and safety studies, notwithstanding trade secret claims under Section 10(b). In 1973, EPA issued a policy statement saying it planned to use the health and safety studies submitted by others in reviewing new applications under section 3(c)(1)(D) (i.e., notwithstanding its reference to Section 10(b)).³⁵ In a 1975 proposal under FOIA, EPA proposed to exclude health and safety studies from confidentiality review procedures because “EPA believes as a matter of public policy, data concerning the effects of such pesticides on humans cannot qualify for confidential treatment,” and because FIFRA suggested that “safety, toxicity, and efficacy test data should be available for public inspection.”³⁶ However, information “[w]hich relates to formulas of products” would only be disclosable under limited circumstances.³⁷

A key development occurred in March 1976, when the EPA General Counsel issued an opinion on the meaning of FIFRA § 10(b), saying that with certain exceptions, “I conclude that none of the test data in the categories listed above [including hazard data] are entitled to confidential treatment under § 10(b).” Significantly, while finding that health and safety studies generally are subject to public disclosure, the EPA General Counsel held that disclosure of confidential chemical identities was both prohibited by FIFRA § 10(b) and not required by the public interest in disclosure:

Disclosure of the confidential formula of a pesticide, as defined above, would further neither the § 3(c)(1)(D) mandatory licensing scheme nor the § 3(c)(2) policy favoring data scrutiny. However, disclosure would often reveal a firm’s manufacturing process. Moreover, confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely. If inquiry shows that the information is in fact confidential in the submitter’s hands, and that its disclosure would be likely to cause substantial harm to the submitter’s competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should

³¹ FIFRA § 3(c)(2), as added by FEPCA (emphasis added).

³² Emphasis added. Note that “trade secrets or commercial or financial information obtained from a person and privileged or confidential” is a reference to exemption (b)(4) of FOIA. TSCA § 14(a) also relies on exemption (b)(4) of FOIA as the basis for protecting trade secret information from disclosure.

³³ As amended by FEPCA, FIFRA § 2(q)(2)(A) provides that a pesticide is misbranded if its label does not bear an “ingredient statement,” a term defined in § 2(n) to include “the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticides . . .” Thus, Congress did not require disclosure of the identity of inert ingredients.

³⁴ S. Rep. No. 92-270 at 20 (1972), 1972 U.S.C.C.A.N. 4092, 4104-05.

³⁵ 38 Fed. Reg. 31862 (Nov. 19, 1973).

³⁶ 40 Fed. Reg. 21,987, 21,991 (May 20, 1975).

³⁷ Id. at 22001.

be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.³⁸

The General Counsel also found manufacturing and quality control information to be protected from disclosure under Section 10(b), even when found in a health and safety study, as well as information supporting applications not yet approved. EPA cited this opinion in September 1976 in finalizing its 1975 FIFRA FOIA proposal.³⁹

Once the General Counsel issued his opinion, EPA began issuing notices informing registrants of its intention to make their studies available to the public. Several registrants sought to prevent disclosure by initiating lawsuits that challenged the General Counsel's opinion that health and safety studies were not confidential. The first such suit was filed in June 1976,⁴⁰ while the House bill with a provision that became Section 14(b) was still in committee.⁴¹

C. Congressional Consideration of TSCA in 1975-1976

This debate under FIFRA figured significantly in the 1975 hearings, the 1976 House bill, and the enactment of TSCA § 14(b).

1. Stakeholder Comments on Disclosure of Health and Safety Studies

The issue of making health and safety studies public was raised numerous times by NGOs in their testimony to EPA in 1975. See, for example, the following statements:

If science is to flourish the findings must be public. Since the dawn of the scientific revolution any suppression of scientific information has been regarded as antiscientific and repressive. Yet the walls of trade secrecy and corporate confidentiality restrict the dissemination of knowledge about the nature and properties of chemicals.⁴²

In particular, the final Subcommittee bill should specify that data from health and safety studies reported to the Administrator pursuant to sections 5 and 8 . . . are not to be considered proprietary information or subject to protection as trade secrets. The effective implementation of a Toxic Substances Control Act requires that information concerning the

hazardous nature of substance be available to the public.⁴³

An NGO representative explicitly referenced the ongoing debate under FIFRA about whether health and safety studies were protected from disclosure as trade secrets:

Under the Pest Control Act, reported out of this committee in 1972, toxicology data on pesticides is not a trade secret. Under the current bill, toxicology appears to be a trade secret, since there is no explicit provision for release⁴⁴

Even as they advocated for disclosure of health and safety studies submitted under TSCA, however, several NGO representatives acknowledged that trade secret chemical identities should remain confidential. One said that "secret formulas" should remain confidential, so long as effects information is made public:

In summary, we support the language in the Brodhead Bill, which would withhold bona fide trade secrets such as secret formulas and secret manufacturing methods, but which would disclose health and safety data or publicly-known manufacturing methods.⁴⁵

Another stated, "Well, we are certainly not advocating that legitimate trade secret information be turned over." However, he maintained that health and safety studies were not trade secrets.⁴⁶ A third said, "If there are studies which give you detailed information on the chemical itself, I think the companies might have a legitimate [trade secret] claim."⁴⁷

Industry also emphasized the importance of protecting trade secrets, particularly confidential chemical identities. For example, one industry representative stated:

Legislation should offer strict control of manufacturers' trade secrets. The chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see and use. Similarly, disclosure of detailed information on formulations, that is, a mixture of materials, should be avoided. Disclosure of all such information can have particularly severe competitive repercussions abroad, in those foreign countries whose manufacturers are not or do not feel restricted by patents or other agreements.⁴⁸

A significant development occurred in September 1975 with the release of a report by the National Academy of Sciences, which EPA had commissioned so as to

³⁸ Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.-A.G.C.) (emphasis added).

³⁹ 41 Fed. Reg. 36,902, 36,924 (Sept. 1, 1976). The final regulation, unamended since 1976, reads, "Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee." 40 C.F.R. § 2.307(g)(4). This language is adapted from FIFRA § 10(a), as added by FEPCA.

⁴⁰ See A. Gabbay, *The Confidentiality of Test Data Under FIFRA*, 2 *Harvard Environmental L. Rev.* 378, 388 (1978) (citing cases).

⁴¹ H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), *Legis. Hist.* at 371-72.

⁴² Statement of Alfred J. Fritsch, Center for Science in the Public Interest, 1975 House Hearings at 172.

⁴³ Statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 185.

⁴⁴ Statement of Peters D. Willson, National Wildlife Foundation, "Toxic Substances Control Act: Hearings Before the Subcommittee on the Environment of the Senate Committee on Commerce," 94th Cong., 1st Sess. (1975) (1975 Senate Hearings) at 158.

⁴⁵ Statement of Anita Johnson, Public Citizen Health Research Group, 1975 House Hearings at 355.

⁴⁶ Statement of Dr. Sidney Wolfe, Health Research Group, 1975 Senate Hearings at 168-69.

⁴⁷ Statement of Jacqueline Warren, Environmental Defense Fund, 1975 Senate Hearings at 171.

⁴⁸ Statement of Orin Smith, M. & T. Chemical Co., 1975 Senate Hearings (Part 2) at 121.

influence the drafting of TSCA. The report recommended that health and safety studies be made publicly available, but not proprietary information in those studies:

Any information available to an agency on the hazards of a chemical that is regulated by that agency should not be considered proprietary and should be available for public inspection in a timely fashion during and after the decision-making process.

The report focused on effects and exposure data such as "data on the intrinsic toxicological properties of a given substance" and "data on patterns and quantities of use." The report agreed, however, that "proprietary" data should be protected from disclosure unless essential to evaluation of the hazard.⁴⁹ While the report did not refer specifically to proprietary chemical identities, EPA subsequently addressed that issue, finding that a structurally descriptive generic name can mean that disclosure of the specific chemical identity "is not necessary to interpret a health and safety study."⁵⁰ See section VI of this paper. The report's recommendation was quoted in the TSCA hearing statements of two NGO representatives.⁵¹

2. The 1976 Provision on Disclosure of Health and Safety Studies

In May 1976, two months after issuance of the General Counsel's opinion, the House responded to these comments by including in a new TSCA bill a provision that would explicitly exclude health and safety studies from confidentiality protection, H.R. 14032.⁵² With minor editing, that provision became TSCA § 14(b). The House report accompanying H.R. 14032 explained:

The purpose of subsection (b) is to clarify that health and safety information is not entitled to confidential treatment either under subsection (a) or the Freedom of Information Act. The subsection should not be construed to imply that in the absence of such a provision, health and safety information would be entitled to such confidential treatment.⁵³

This statement is a clear reference to the then-ongoing debate under FIFRA of whether health and safety studies were protected from disclosure as trade secrets, and reflected the opinion of the EPA General Counsel that they were not so protected.

The House bill and report did not, however, endorse public disclosure of confidential information of competitive value that might be contained in the health and safety studies. Notwithstanding Section 14(b), the House report provided assurance that Section 14 would protect the "competitive position" of submitters of information to EPA:

However, the Committee recognizes that some information which the Administrator may obtain will be of tremendous competitive value to the person providing it. Accordingly, section 14 contains specific prohibitions against release of such information so that the competitive position of those supplying the information will be protected.⁵⁴

It would be inconsistent with this statement that Section 14 protects "the competitive position of those supplying the information" to consider that the exemption from confidentiality protection for health and safety studies mandates disclosure of competitively sensitive composition information. While Section 14(b) does not list composition information specifically as exempt, neither does it specifically mandate disclosure of composition information. Indeed, in describing what a health and safety study is, the Conference Committee emphasized information related to effects, saying nothing about composition information:

It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included.⁵⁵

The EPA General Counsel opinion specifically found in the FIFRA context that nondisclosure of confidential composition information would not impact the purposes of public disclosure of health and safety studies; the same reasoning applies to the TSCA context as well.

As proposed and adopted, Section 14(b) has an exemption for "portion of mixture" information. The House report commented on this provision:

In referring to data "disclosing the portion of the mixture comprised by any of the chemical substances in the mixture," the Committee intends to **protect confidential trade secret information respecting the specific formulation of a mixture.** However, the Committee does not intend to prohibit the Administrator from disclosing the chemical substances comprising the mixture by their order of quantity in the mixture.⁵⁶

The "specific formulation of a mixture" clearly refers to both the names of the ingredients as well as their percentages, as seen in the FEPCA references to protecting "information relating to formulas of products"⁵⁷ and "information relative to formulas of products,"⁵⁸ where those provisions have always been interpreted to include the identities of confidential inerts as well as their respective percentages.

The reference to "order of quantity in the mixture" is a reference to the Fair Packaging and Labeling Act (FPLA), enacted 10 years earlier, which mandates that ingredients in consumer products be disclosed on labels "in order of decreasing predominance" while protect-

⁴⁹ National Academy of Sciences, *Decision Making for Regulating Chemicals in the Environment* (1975), at 28 (italics in original).

⁵⁰ 40 C.F.R. § 720.90(c)(3), 725.92(c)(2).

⁵¹ Statement of Linda M. Billings, Sierra Club, in 1975 House Hearings at 165, and statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 178.

⁵² H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), H.R. Rep. No. 94-1341 at 176-77 (1976), Legislative History of the Toxic Substances Control Act (1976) (Legis. Hist.) at 371-72.

⁵³ H.R. Rep. No. 94-1341 at 51, Legis. Hist. at 458.

⁵⁴ H.R. Rep. No. 94-1341 at 50 (1976), Legis. Hist. at 457.

⁵⁵ H.R. Rep. No. 94-1679 at 58 (1976), Legis. Hist. at 671 (emphasis added).

⁵⁶ H.R. Rep. No. 94-1341 at 51 (1976), Legis. Hist. at 458 (emphasis added).

⁵⁷ FIFRA § 10(b).

⁵⁸ FIFRA § 14(b)(3).

ing trade secrets. It provides that the Federal Trade Commission (FTC) or Food and Drug Administration (FDA) may promulgate regulations to:

require that the label on each package of a consumer commodity . . . bear . . . in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in **order of decreasing predominance**, but nothing in this paragraph shall be deemed to require that any trade secret be divulged . . .⁵⁹

In other words, the order of ingredients by decreasing predominance was not considered a trade secret, but such mandated disclosure was coupled with a prohibition on disclosure of trade secrets (both ingredient names if trade secret and portion of mixture information). In 1973, FDA adopted regulations for cosmetic labeling under the FPLA which required disclosure of intentionally added ingredients “in descending order of predominance,” but with a mechanism whereby FDA could rule on claims that ingredient identities were trade secrets, in which case they would be identified as “other ingredients.”⁶⁰ In 1975, FDA amended those regulations⁶¹ and made them effective starting in 1976.⁶² Thus, the issue of ingredient disclosure in descending order was a current topic when the provision that became Section 14(b) was introduced and considered.

In short, the reference to disclosure of mixture components “by their order of quantity in the mixture” is not an implicit call for public disclosure of trade secret chemical identities, as EPA has suggested.⁶³ Rather, it is a repetition of a decade-old legislative determination that order of predominance is not a trade secret. Since that determination from the FPLA contained, within the same sentence, a prohibition on disclosure of trade secret ingredient names, the reference in Section 14(b) to “order of quantity” actually strengthens the conclusion that TSCA protects trade secret chemical identities.

During Senate consideration of the conference-approved bill, Sen. Warren Magnuson (D-Wash.) referred to “mixture composition” information as an exception to Section 14(b).⁶⁴ This statement by a member of the Conference Committee, one of the leading proponents of TSCA in the Senate, indicates the expectation that information in health and safety studies on “mixture composition,” not just portion of mixture information, would not be disclosed as part of health and safety studies.

In summary, the legislative history of TSCA demonstrates continued congressional concern for protecting critical competitive information from public disclosure,

specifically including trade secret or confidential chemical identity information.

V. TSCA as Part of a Series of Statutes Mandating Disclosure of Health and Environmental Information on Chemicals But Not Confidential Chemical Identities

TSCA was the second of six chemical-related statutes that Congress enacted within a 15-year period to mandate that health and environmental information submitted to EPA be made public. Besides TSCA, the statutes include the Federal Environmental Pesticide Control Act of 1972 (FEPCA); the Federal Pesticide Act of 1978 (FPA); the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA); the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA); and the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title I. These other statutes all protect confidential competitive information in or underlying the health and environmental information from disclosure. In light of these statutes, it is even clearer that TSCA does so also.

A. Federal Environmental Pesticide Control Act of 1972

As noted in Section III.A. above, FEPCA required disclosure of health and safety studies submitted to EPA under FIFRA, but it protected confidential competitive information from disclosure, using the standards of FOIA exemption 4. Several provisions explicitly protected confidential formula information, including the identity of confidential inerts, from disclosure.

B. Federal Pesticide Act of 1978

The controversy under FEPCA about whether health and safety studies were protected from disclosure continued past the enactment of TSCA. In 1978 with FPA, Congress applied the solution adopted in TSCA § 14(b) to FIFRA, saying that health and safety studies were not protected from disclosure, but proprietary information in those studies, including trade secret identities of inerts, were protected from disclosure, except under unusual circumstances.

Twelve months after enactment of TSCA, a House committee reported a FIFRA bill (H.R. 8681) that would:

Clarify the prohibition against public disclosure of “trade secret” information obtained by the Environmental Protection Agency through the registration process. Data showing test results would not be considered “trade secrets.” Data relating to the manufacturing process or quality control process, **or to the identity or percentage quantity of inert ingredients** . . . could not be made public unless the Administrator determined it necessary to protect against an unreasonable risk of injury to health or the environment subject to prescribed procedures . . .

H.R. 8681 also clarifies the trade secret provisions of the Act by **balancing the legitimate right of the public to know the basis for agency decisions and the right of a business to see that the manufacturing process and other trade secret information controlled by the Act are not disclosed to the commercial advantage of competing business owners** . . .

⁵⁹ Fair Packaging and Labeling Act, Pub. L. 89-755 (1966), § 5(c)(3), 15 U.S.C. § 1454(c)(3) (emphasis added).

⁶⁰ 21 C.F.R. § 1.205(a), 38 Fed. Reg. 28912, 28913 (Oct. 17, 1973). FTC has not adopted implementing regulations. See 36 Fed. Reg. 12284, 12286 (June 30, 1971), which reserved 16 C.F.R. §§ 502.200-502.299 (“Common Name and Ingredient Listing”).

⁶¹ 40 Fed. Reg. 8918 (Mar. 3, 1975). The current provision is codified at 21 C.F.R. § 701.3.

⁶² 40 Fed. Reg. 8924 (Mar. 3, 1975).

⁶³ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979); EPA, Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA (2003), OPPT-2002-0067-0002, Docket No. OPPT-2002-0067, at 35-36.

⁶⁴ Cong. Rec., Sept. 28, 1976, Legis. Hist. at 730.

This provision is intended to protect the secrecy of manufacturing methodology, the **confidential formula of a formulated product**, and the means of analysis of a formulated product to determine its inert ingredients.⁶⁵

In 1978, Congress accepted the House language and added a new FIFRA § 10(d) that declared that health and safety studies submitted under FIFRA in connection with registered pesticides “shall be available for disclosure to the public.” However, that provision was limited to include the limitations on disclosure identified in the General Counsel’s 1976 opinion:

Provided further, That this paragraph does not authorize the disclosure of information that—

(A) discloses manufacturing or quality control processes, . . .

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.⁶⁶

In other words, Congress required disclosure of health and safety studies, but not the trade secret or confidential identities of the chemicals tested, except where EPA’s balancing of the competing interests required a different outcome. This is the same resolution that Congress provided in TSCA § 14, two years earlier, only somewhat less explicitly.

C. Comprehensive Environmental Response, Compensation, and Liability Act of 1980

Two years later, in 1980, Congress enacted CERCLA. Section 104(e)(2)(A) provided that all information obtained under the response authority “shall be made public” unless the person providing the information establishes that disclosure would “divulge information entitled to protection under section 1905 of title 18 of the United States Code,” i.e., the Trade Secrets Act.⁶⁷ There is an exception for “health or safety effects data,” which are not protected from disclosure. This exception more clearly expresses the intent of TSCA’s exception for health and safety studies. Note that in EPCRA (discussed next), effects data are also not protected from disclosure, but chemical identities may be protected.

D. Emergency Planning and Community Right-to-Know Act of 1986

In 1986, Congress enacted EPCRA to require disclosure of chemical-related information to EPA, state and local authorities, and the public.⁶⁸ The provision on trade secrets, Section 322, protects from public disclosure *only* “specific chemical identities (including chemical name and other specific identification).”⁶⁹

Where the identity of a chemical is withheld from the public, information about the adverse effects of the chemical must be disclosed.⁷⁰

This provision reflects congressional balancing of the competing interests in disclosure and nondisclosure. Information other than chemical identity is not protected. To provide the public with some information about chemicals whose identities are withheld, Section 322 requires that the submitter identify “the generic class or category” of the chemical.⁷¹ An up-front substantiation of trade secrecy is required, including a showing that the chemical identity “is not readily discoverable through reverse engineering.”⁷² i.e., that it actually is a trade secret.

The legislative history refers to EPA’s experience with generic names under TSCA, as required under TSCA § 5(d)(2):

The Administrator may give guidance for choosing such [generic] classes or categories in implementing regulations, drawing upon experience under the Toxic Substances Control Act.⁷³

More than FIFRA or TSCA, EPCRA is intended to provide the public with information about chemicals. That Congress chose to protect trade secret chemical identities even under this statute shows the continuing congressional concern with balancing the interest in disclosure of health and safety information with the interest in protecting confidential competitive information, a balancing also present in TSCA. Congress mandated non-disclosure of trade secret chemical identities if certain requirements are met, but disclosure of structurally descriptive generic names, i.e., the same resolution reached in TSCA § 5(d)(2).

E. Superfund Amendments and Reauthorization Act of 1986, Title I

EPCRA is Title III of SARA and essentially a standalone statute. Title I amended CERCLA to cut back on the broad protection from disclosure granted by simple reliance on the Trade Secrets Act. It added several restrictions, including that the person submitting the information establish that “[t]he specific chemical identity, if sought to be protected, is not readily discoverable through reverse engineering,” thereby conforming CERCLA to the trade secret provisions of EPCRA.⁷⁴ It also prohibited confidentiality protection for information on the physical properties and health and environmental hazards of the hazardous substances, as well as “[t]he trade name, common name, or generic class or category of the hazardous substance.”⁷⁵ Specific chemical identities, however, could be protected from disclosure.

F. Implications for TSCA

Each of these five statutes regulating chemicals mandated disclosure of health and safety information, but protected confidential chemical identities from disclo-

⁶⁵ H. Rep. No. 95-663, at 16, 18 (1977), 1978 U.S.C.C.A.N. 1989, 1991-92, 2005-06 (emphasis added).

⁶⁶ Federal Pesticide Act of 1978, Pub. L. 95-396 (1978), § 15(2), 7 U.S.C. § 136h(d) (emphasis added).

⁶⁷ Pub. L. 96-510 (1980), § 104(e)(2)(A), 42 U.S.C. § 9604(e)(7)(A).

⁶⁸ EPCRA is Title III of SARA, Pub. L. 99-499, 42 U.S.C. § 11001 et seq.

⁶⁹ EPCRA § 322(a)(1), 42 U.S.C. § 11042(a)(1).

⁷⁰ EPCRA § 322(h), 42 U.S.C. § 11042(h).

⁷¹ EPCRA § 322(a)(2), 42 U.S.C. § 11042(a)(2).

⁷² EPCRA § 322(b), 42 U.S.C. § 11042(b).

⁷³ H. Conf. Rep. No. 99-962 (1986) at 303, 1986 U.S.C.C.A.N. 3276, 3396.

⁷⁴ Id. at 197, 1986 U.S.C.C.A.N. at 3290.

⁷⁵ Pub. L. No. 99-499 (1986), § 104(n), amending CERCLA § 104(e) (adding CERCLA § 104(e)(7)(E) and (F)).

sure, either explicitly or by implication, with provisions similar to what appears in TSCA § 14. None prohibited trade secret claims for chemical identities, although some imposed criteria for those claims.

TSCA similarly provides broad protection for trade secrets and confidential information in Section 14(a). Its main reservation from that protection, in Section 14(b), is for health and safety studies, which are not protected from disclosure. This limitation is similar to the requirement in several of these statutes that health and environmental effects data must be made public. Just as none of those statutes required disclosure of confidential chemical identities, so TSCA does not do so either.

VI. EPA Recognition of Its Need to Balance Disclosure of Health and Safety Studies With Protection of Trade Secret or Confidential Chemical Identities

Early in its implementation of TSCA, EPA recognized that "Congress was clear in section 14 that confidentiality should be preserved to the maximum extent practicable without impairing the regulatory scheme of TSCA."⁷⁶ Despite the language of Section 14(b), it concluded:

Accordingly, EPA is not persuaded that Congress intended the Agency to take a mechanical approach to disclosure of a specific chemical identity as part of a health and safety study.⁷⁷

The 1983 final PMN rule developed the idea that, consistent with Section 14(b), EPA could balance the public's interest in access to health and safety information with industry's competitive interest in protecting trade secret chemical identities. This balancing was to be achieved through disclosure of structurally descriptive generic names, an approach endorsed by TSCA § 5(d)(2) and proposed in the 1972 Senate report.⁷⁸ The preamble stated:

As EPA stated in the January 1979 proposal, the Agency considers the specific chemical identity always to be part of a health and safety study even when it does not appear in the study. Consequently, the chemical identity would be subject to the disclosure requirements of section 14(b). However, in many cases the chemical identity is one of the most commercially sensitive pieces of information in the section 5 notice. Because of the substantial concern expressed by industry about the harm of disclosing confidential chemical identities, EPA explored ways of limiting the commercial harm of such disclosure while still meeting the requirements of section 14(b) of TSCA and providing the public with adequate information about health and safety studies

This issue generated a great deal of comment. Industry has expressed its concerns about disclosure of confidential chemical identities at any time, while public interest groups and others are concerned that health and safety studies would be meaningless without knowledge of the specific chemical identity in-

involved. In an attempt to meet both these concerns, **EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA**

Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies.

This solution will result in disclosure of a confidential chemical identity only when it is necessary to interpret a health and safety study, unless disclosure would reveal confidential process or mixture information that is protected under section 14(b). This meets concerns expressed by both industry and public interest groups. Industry was concerned that a rule mandating disclosure even when disclosure would not serve any public interest would unnecessarily penalize companies conducting health and safety studies. On the other hand, **public interest groups were concerned that disclosure of health and safety studies without the identity of the substance involved would be meaningless if knowledge of the specific identity were necessary to understand the study.** Under this approach, companies will be able to present arguments that disclosure of the specific chemical identity is not necessary to interpret a study and, at the same time, members of the public requesting access to studies will be able to argue why disclosure of the specific identity is necessary.

This solution to the issue of confidential chemical identities also has an impact on development of generic chemical names. Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. **Sufficiently specific generic names will tend to support arguments that disclosure of the specific chemical identity is not necessary to understand the study.**⁷⁹

In other words, EPA recognized that, like other proprietary commercial information, confidential chemical identities (including those that do not reveal process or portion of mixture information) in a health and safety study fall within the protection of section 14(a). That protection mandate must be balanced against the disclosure mandate of section 14(b). The competing interests can and should be balanced through disclosure of appropriate generic names.

A decade later, EPA reaffirmed this approach in the preamble to 1993 proposed amendments to the PMN rules⁸⁰ and in the preamble to the 1994 proposed rule on microbial products of biotechnology.⁸¹

⁷⁶ 42 Fed. Reg. 64572, 64591 (Dec. 23, 1977).

⁷⁷ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).

⁷⁸ S. Rep. No. 92-783 at 19-20 (1972).

⁷⁹ 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added).

⁸⁰ 58 Fed. Reg. 7661, 7666 (Feb. 8, 1993).

⁸¹ 59 Fed. Reg. 45,526, 45,553-54 (Sept. 1, 1994).

EPA has announced that it plans to initiate rulemaking to delete these generic name provisions in its regulations, apparently on the basis that under Section 14(b) it had no authority to adopt them.⁸² EPA certainly had authority to adopt those provisions, just as it had authority under Section 8(d) to exclude proprietary information such as company name, financial statistics, and product codes from studies otherwise disclosed to the public.⁸³ EPA's authority for all these provisions is Section 14(a). All this information may be a part of a study submitted under TSCA, but it is nevertheless protected from disclosure. Because chemical identity can also impact public understanding of the study, however, EPA properly adopted provisions for disclosure of appropriate generic names so as to balance the competing interests.

VII. Steps EPA Should Take to Protect Confidential Chemical Identities

In light of the information provided in this paper, EPA should take the following specific steps to provide appropriate protection for confidential chemical identities in submitted health and safety studies and in other contexts.

A. EPA Should Revise Its Regulations and Guidance to Allow Confidentiality Claims for Confidential Chemical Identities in Studies Where Appropriate

EPA's regulations and guidance currently preclude all or most confidentiality claims for chemical identities in or underlying studies.⁸⁴ In light of the foregoing discussion, EPA should amend those regulations and revise that guidance to allow CBI claims for chemical identities where appropriate.

EPA's Spring 2011 Regulatory Agenda identifies a planned initiative, RIN 2070-AJ87, to adopt amendments to its PMN and MCAN rules to delete provisions allowing CBI claims for confidential chemical and microorganism identities in data from health and safety studies submitted under TSCA prior to the commencement of manufacture. It targets 40 C.F.R. §§ 720.90(c) and 725.92(c). EPA submitted this proposal to the Office of Management and Budget on December 27, 2011. EPA should not proceed with this initiative.

Section VI of this paper discusses EPA's reasoning for adopting those requirements in the 1980s and 1990s. At the time, EPA took extensive comments and thoroughly considered the scope of Section 14 and its legal authority. Nothing has occurred since then that should cause EPA to conclude now, 35 years after enactment of TSCA, that its longstanding interpretation of Section 14 allowing confidentiality claims under strictly limited conditions is inconsistent with TSCA and that Section 14 necessitates deleting those regulatory provisions.

⁸² EPA, Spring 2011 Regulatory Agenda (July 7, 2011) at 277.

⁸³ See 40 C.F.R. § 716.55(a)(3).

⁸⁴ See 40 C.F.R. § 716.55 (section 8(d) regulations); 40 C.F.R. § 720.90(b) (PMN regulations); 40 C.F.R. § 725.92(b) (MCAN regulations); 68 Fed. Reg. 33129, 33136 (June 3, 2003) and 75 Fed. Reg. 3462 (Jan. 31, 2010) (section 8(e) guidance); 75 Fed. Reg. 29754 (May 27, 2010) (general guidance).

B. EPA Should Consider Requiring Generic Names for Trade Secret or Confidential Chemical Identities in Health and Safety Studies and Requiring Up-Front Substantiation of CBI Claims for Studies

EPA already requires up-front substantiation for CBI claims in studies submitted under sections 4, 5, and 8(e).⁸⁵ EPA does not require up-front substantiation for CBI claims for submissions under section 8(d)⁸⁶ or section 5(h)(4).⁸⁷ It should require up-front submission of all CBI claims for chemical identities.

A key reason for EPA's current position that it must disclose trade secret or confidential chemical identities in studies is its belief that without some knowledge of what chemicals were studied, the public has no way to evaluate the study. Steve Owens, then assistant EPA administrator for chemical safety and pollution prevention, has said, "[a] health and safety study with the chemical name kept secret is completely useless to the public."⁸⁸ This position is contradicted by EPA's findings in 1983, 1993, and 1994 that in some circumstances "[t]he specific chemical identity is not necessary to interpret a health and safety study," as explained in Section VI above.

As EPA previously recognized, in order to make studies meaningful to the public, it is not necessary to require disclosure of chemical identities in every case. Instead, requiring submission of structurally descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Such generic names can provide the public with detailed information about the structure of the chemical, thus allowing linkage to the scientific literature on similar chemicals and permitting an assessment of the suitability of study methods. In contrast, specific chemical names are sometimes of little value to the public, since there may be no published scientific literature on the specific chemical, particularly in the case of new or recently developed chemicals.

There is ample congressional precedent for the disclosure of structurally descriptive generic names instead of specific chemical identities. The use of such generic names is called for in Section 5(d)(2), in EPCRA, and in SARA Title I. As noted above, the legislative history of the EPCRA generic name provision cited EPA's experience with generic names under TSCA with approval.

Aside from the examples cited above, EPA has on numerous occasions required disclosure of generic names instead of specific chemical identities as a way of balancing the competing interests. EPA chose to require the use of generic names for entries in the confidential TSCA Inventory,⁸⁹ even though "Congress did not seem

⁸⁵ 40 C.F.R. §§ 720.85(b)(3)(iv) (PMNs), 725.94 (MCANs), 790.7(c) (section 4 submissions), and 68 Fed. Reg. 33129, 33140 (June 3, 2003) (section 8(e) submissions).

⁸⁶ See 40 C.F.R. § 716.55.

⁸⁷ See 40 C.F.R. § 723.50(f), 723.175(k).

⁸⁸ EPA press release, "EPA Removes Confidentiality Claims for More Than 150 Chemicals / Part of continuing effort to protect Americans' health by increasing access to chemical information" (June 8, 2011), available at <http://yosemite.epa.gov/opa/admpress.nsf/a543211f64e4d1998525735900404442/9f7964fcbca3824a852578a900574cea?OpenDocument> 35 CRR 579, 6/13/11.

⁸⁹ 40 C.F.R. § 710.7(f), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).

to contemplate that the fact that certain chemical substances are manufactured or processed for commercial purposes would be claimed as confidential.” EPA explained that in deciding to require the use of generic names it “had to balance the competing concerns of section 14 and sections 8(a) and 5(b).”⁹⁰ EPA has adopted generic name requirements in its regulations implementing Section 5,⁹¹ Section 8(b),⁹² and EPCRA § 322.⁹³

As articulated in the PMN and MCAN regulations, EPA has identified the key question as whether the specific chemical identity is “necessary to interpret a health and safety study.” This is a different question than whether the public must have the chemical substance’s CAS number in order to access the published toxicological literature of *other* studies on the same chemical substance. That makes sense, particularly with respect to recent PMN substances, which are highly unlikely to be the subject of published toxicological literature. In that context, a generic name can provide sufficient information to interpret that study.

Moreover, a generic name may be used to access the toxicological literature on structurally related compounds. In many cases, a search on Toxline, a common tool for searching the toxicological literature, using a CAS number or CAS name will identify few, if any, studies. In contrast, searching on a generic name for the same chemical substance may identify a significant number of studies. This may be seen by searching on Toxline using specific chemical names, CAS numbers, and generic names for the same chemicals.

In 2009, EPA changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential.⁹⁴ EPA had previously associated generic names with those chemical substances. In many cases, a Toxline search for a generic name for a declassified substance identified more studies than did Toxline searches for the corresponding CAS number and CAS name. For example:

- EPA associated the generic name “alkyl salicylaldehyde” with benzaldehyde, 5-dodecyl-2-hydroxy-, CAS No. 77635-21-3.
 - A Toxline search on “salicylaldehyde” identified 279 studies.
 - Toxline searches on the CAS name and on the CAS number identified no studies.
- EPA associated the generic name “silane, dichloro(chloroalkyl)alkyl-” with silane, dichloro(3-chloro-2-methylpropyl)methyl-, CAS No. 1628-11-1.
 - A Toxline search on “dichlorosilane” identified 27 studies.
 - Toxline searches on the CAS name and on the CAS number identified no studies.

⁹⁰ Id. at 64590. See 44 Fed. Reg. 2242, 2255 (Jan. 10, 1979) (similar language in proposed PMN provision on generic names).

⁹¹ 40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3),); former 40 C.F.R. § 723.250(f)(2)(x), 49 Fed. Reg. 46066, 46088 (Nov. 21, 1984).

⁹² Former 40 C.F.R. § 710.7(e)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).

⁹³ 40 C.F.R. § 350.5(f).

⁹⁴ 74 Fed. Reg. 37224 (July 28, 2009).

- EPA associated the generic name “disubstituted quinolone” with 2,3-quinolinedicarboxylic acid, CAS No. 643-38-9.
 - A Toxline search on the generic name identified 21 studies.
 - Toxline searches on the CAS name and on the CAS number identified one study.
- EPA associated the generic name “alkylpridinium halide” with pyridinium, 1-dodecyl-, bromide (1:1), CAS No. 104-73-4.
 - A Toxline search on “alkylpridinium” identified 38 studies.
 - Toxline searches on the CAS name and CAS number identified 13 studies.
- EPA associated the generic name “pyrimidinamine, disubstituted” for two of the declassified identities.
 - A Toxline search on “pyrimidinamine” identified 118 studies.
 - One of the declassified chemical substances with that generic name was 2-pyrimidinamine, 4,6-dimethoxy-, CAS No. 36315-01-2. Toxline searches on the CAS name and on the CAS number identified one study.
 - The other declassified chemical substance with that generic name was 2-pyrimidinamine, 4-chloro-6-methoxy-, CAS No. 5734-64-5. Toxline searches on the CAS name and on the CAS number identified two studies.

In short, generally, a structurally descriptive generic name is sufficient for interpreting a submitted health and safety study, and that same generic name can be more effective than the specific chemical name or CAS number for identifying studies on the same or related compounds in the toxicological literature.

C. EPA Should Work With Industry and NGOs to Improve Development of Generic Names

EPA has complained that “CBI procedures consume an inordinately large amount of Agency resources that may not be justified.”⁹⁵ In particular, negotiations between EPA and a submitter about appropriate generic names may be onerous. The solution is for EPA, industry, and NGOs to work together to improve the process for identifying appropriate generic names and thereby expedite those negotiations.

EPA has provided some guidance on how to develop generic names,⁹⁶ but that guidance has not been updated in over 25 years. As EPA has recognized, the guiding principle should be that “[t]he proposed generic name must be only as generic as necessary to protect the identity of the particular chemical substance.”⁹⁷ Congress endorsed that principle in EPCRA and SARA Title I, where it called for disclosure of “the generic class or category” rather than a highly detailed generic name. The legislative history of that provision in EPCRA states:

⁹⁵ 58 Fed. Reg. 7661, 7666 (Feb. 8, 1993).

⁹⁶ “Generic Names for Confidential Chemical Substance Identities,” Appendix B to Vol. I of the Toxic Substances Control Act Chemical Substance Inventory (1985), <http://www.epa.gov/opptintr/newchems/pubs/genericnames.pdf>

⁹⁷ Id. at 64591.

The generic class or category of chemical may be defined as broadly as is needed to protect the specific chemical identity from disclosure, but, consistent with the purpose of this title to provide information to the community and the public, it should be defined no more broadly than necessary to afford such protection.⁹⁸

EPA now has decades of experience in developing generic names. It should work with industry and NGOs to memorialize that experience in the form of detailed guidance. Such guidance, reflecting the input of industry, will go a long way toward reducing the resources needed for determining appropriate generic names.

D. EPA Should Allow CBI Claims for Chemical Identities in Studies Where Appropriate

EPA has announced that “[w]here a chemical identity [in or underlying a study] does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment.”⁹⁹ As explained above, EPA should follow the requirements of Section 14(a) and in appropriate cases accord CBI protection for those chemical identities. As it reviews studies with CBI claims for chemical identities (e.g., in its ongoing review of historical CBI claims), EPA should allow those claims, at least where substantiation of continuing CBI status is provided. EPA should consider requiring disclosure of an appropriate generic name as a condition for nondisclosure.

E. EPA Should Allow CBI Claims for Chemical Identities in R&D Mixtures Where Appropriate

Of particular concern to much of industry is the situation where product formulations under development are tested, then those studies are submitted under TSCA. In almost all cases, the formulations contain only existing chemical substances, but the combination of the particular components may be highly innovative. EPA has indicated that it expects to release to the pub-

lic chemical identities in or underlying studies submitted under Section 8(e) where the chemical identities appear on the public TSCA Inventory. Presumably, this includes mixtures of chemical substances, all of whose identities appear on the public Inventory. Where those mixtures are for R&D products, however, EPA should not require disclosure.

As explained in section III.F of this paper, Section 14(b) of TSCA applies to a submitted study with respect to “any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution.” A mixture that has not “been offered for commercial distribution” at the time of disclosure because it is at the R&D stage or has otherwise never been commercialized is not covered by that provision, even if its components are on the public Inventory. Accordingly, EPA should not disclose its components just because a study on that mixture has been submitted. EPA did disclose the components of such a mixture recently in connection with a Section 8(e) submission by Proctor & Gamble, 8EHQ-94-13020.¹⁰⁰ There the original submission indicated that the mixture was the subject of R&D.

Conclusion

EPA is incorrect in interpreting Section 14(b) to require disclosure of trade secret or confidential chemical identities in or underlying most health and safety studies except where their disclosure would also reveal process or portion of mixture information. Instead, Section 14(a) protects trade secret chemical identities, even in or underlying studies. Section 14(b) is directed at health and safety information, not trade secret or confidential chemical identities.

EPA should continue to balance the interest in disclosure of health and safety information with the interest in protecting trade secrets and confidential information. One way favored by Congress to do this balancing is to require development of generic names, which would be disclosed in lieu of specific chemical identities.

⁹⁸ H. Conf. Rep. No. 99-962 (1986) at 303, 1978 U.S.C. C.A.N. 3276, 3396.

⁹⁹ 75 Fed. Reg. 29754 (May 27, 2010).

¹⁰⁰ Available at <http://www.epa.gov/oppt/existingchemicals/pubs/declassified/actions/6-8-2011/8EHQ-94-13020-89110000315.pdf>

Appointment

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: 10/6/2020 6:33:15 PM
To: Henry, Tala [Henry.Tala@epa.gov]; Le, Madison [Le.Madison@epa.gov]; Camacho, Iris [Camacho.Iris@epa.gov]
CC: Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

Ex. 6 Conference Code

Start: 10/8/2020 6:30:00 PM
End: 10/8/2020 7:30:00 PM
Show Time As: Tentative

-----Original Appointment-----

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Friday, October 2, 2020 8:24 PM
To: Franz, Christina; Dekleva, Lynn
Subject: FW: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

From: Franz, Christina
Sent: Thursday, October 01, 2020 12:58 PM
Required: TSCA Section 5 Group
Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie Mcmichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna); Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne
Subject: TSCA Section 5 EPA Meeting
When: Thursday, October 08, 2020 2:30 PM-3:30 PM.

Ex. 6 Conference Code

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

To join via webex: https://americanchemistry.webex.com/meet/christina_franz

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could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

TSCA Section 5 Work Group Meeting
AGENDA

Ex. 6 Conference Code

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)

[[HYPERLINK "https://americanchemistry.webex.com/meet/christina_franz"](https://americanchemistry.webex.com/meet/christina_franz)]

Time	Topic
2:30 p.m.	Welcome and Introductions <ul style="list-style-type: none">• Antitrust Reminder• Agenda Review
	TSCA Discussion with EPA <ul style="list-style-type: none">• OCSPP Reorganization• Safety Data Sheet Requirements on section 5 submissions• Access to engineering and health assessment reports• EPA's selection of analogues• 2020 EPA Stakeholder Meeting on Section 5• 40 CFR 720 revisions
3:25 p.m.	Next Steps
3:30 p.m.	Adjourn

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

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- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

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- protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.; and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

- rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Revised 3/80 (single page version)

Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

Appointment

From: Franz, Christina [Christina_Franz@americanchemistry.com]
Sent: 10/6/2020 6:33:19 PM
To: Franz, Christina [Christina_Franz@americanchemistry.com]; Henry, Tala [Henry.Tala@epa.gov]; Le, Madison [Le.Madison@epa.gov]; Camacho, Iris [Camacho.Iris@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]
CC: Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]
Subject: TSCA Section 5 EPA Meeting
Attachments: ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf
Location: **Ex. 6 Personal Privacy (PP) - conference code/call in number**
Start: 10/8/2020 6:30:00 PM
End: 10/8/2020 7:30:00 PM
Show Time As: Tentative

-----Original Appointment-----

From: Franz, Christina <Christina_Franz@americanchemistry.com>
Sent: Friday, October 2, 2020 8:24 PM
To: Franz, Christina; Dekleva, Lynn
Subject: FW: TSCA Section 5 EPA Meeting
When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: **Ex. 6 Personal Privacy (PP) - conference code/call in number**

From: Franz, Christina
Sent: Thursday, October 01, 2020 12:58 PM
Required: TSCA Section 5 Group
Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.Lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie McMichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna); Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne
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TSCA Section 5 Work Group Meeting

AGENDA

Ex. 6 Personal Privacy (PP) - conference code/call in number

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)

[HYPERLINK: Ex. 6 Personal Privacy (PP) - conference code/call in number]

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Revised 3/80 (single page version)

Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

Appointment

From: Sullivan, Andrew [sullivan.andrew@epa.gov]
Sent: 11/10/2020 5:45:14 PM
To: Sullivan, Andrew [sullivan.andrew@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Le, Madison [Le.Madison@epa.gov]; Master, Barbora [Master.Barbora@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Lynn L. Bergeson [lbergeson@actagroup.com]
CC: Chad H. Howlin [chowlin@lawbc.com]; lbergeson@lawbc.com; Richard E. Engler, Ph.D. [rengler@lawbc.com]
Subject: Outreach meeting with New Chemicals Coalition on 720 Regulations
Attachments: 720 proposed rule_backgrounder.docx
Location: Microsoft Teams Meeting
Start: 11/10/2020 7:30:00 PM
End: 11/10/2020 8:00:00 PM
Show Time As: Busy

-----Original Appointment-----

From: Sullivan, Andrew
Sent: Thursday, November 5, 2020 9:23 AM
To: Sullivan, Andrew; Dekleva, Lynn; Le, Madison; Master, Barbora; Passe, Loraine; Lynn L. Bergeson
Cc: Chad H. Howlin; Lynn L. Bergeson; Richard E. Engler, Ph.D.
Subject: Outreach meeting with New Chemicals Coalition on 720 Regulations
When: Tuesday, November 10, 2020 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Hello,

Looking forward to hearing your thoughts on proposed changes to the New Chemicals 720 Regulations. **Attached is a one-pager to help guide our discussion.**

Join Microsoft Teams Meeting

Ex. 6 Personal Privacy (PP) - conference code/call in number

United States, Washington DC (Toll)

Conference ID: Ex. 6 Personal Privacy (PP) - conference code/call in number

[Local numbers](#) | [Reset PIN](#) | [Learn more about Teams](#) | [Meeting options](#)

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**Updates to the TSCA Section 5 (New Chemicals) Procedural Regulations (40 CFR part 720)
Summary of the Notice of Proposed Rulemaking (NPRM) for Stakeholder Outreach
November 2020**

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

- What improvements do you recommend to address the inefficiencies in the new chemical notice review process described above?

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/5/2019 5:22:54 PM
To: 'Hartigan, Suzanne' [Suzanne_Hartigan@americanchemistry.com]
CC: Blair, Susanna [Blair.Susanna@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; 'Risotto, Steve' [Steve_Risotto@americanchemistry.com]; Wick, Caryn [Wick@khlaw.com]; Belz, Alyssa L [belz@khlaw.com]
Subject: RE: Coordination Call for GlobalChem Panel
Attachments: Abestos-Globalchem-Berger-20190306.pptx

Please find attached a copy of my presentation – thanks - Tom

From: Berger, Tom C.
Sent: Tuesday, March 5, 2019 8:38 AM
To: 'Hartigan, Suzanne' <Suzanne_Hartigan@americanchemistry.com>
Cc: Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Risotto, Steve <Steve_Risotto@americanchemistry.com>
Subject: RE: Coordination Call for GlobalChem Panel

Hi Suzanne –

Ex. 5 Deliberative Process (DP)

From: Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>
Sent: Tuesday, February 26, 2019 1:35 PM
To: Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Berger, Tom C. <Berger@khlaw.com>; Risotto, Steve <Steve_Risotto@americanchemistry.com>
Subject: FW: Coordination Call for GlobalChem Panel

Dear Susanna, Cathy, Tom and Steve,

Ex. 5 Deliberative Process (DP)

Best,
Suzanne

Suzanne B. Hartigan, Ph.D. | American Chemistry Council
Senior Director, Regulatory and Technical Affairs
suzanne_hartigan@americanchemistry.com
700 2nd Street, NE | Washington, DC | 20002
O: (202) 249-6440
www.americanchemistry.com

From: Hartigan, Suzanne

Sent: Thursday, February 21, 2019 12:21 PM

To: 'Fehrenbacher, Cathy' <Fehrenbacher.Cathy@epa.gov>; Blair, Susanna <Blair.Susanna@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Cc: Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: RE: Coordination Call for GlobalChem Panel

Great, and thanks to all for your quick responses. Let's set the call for Tuesday at 1 PM ET and I will follow up with a calendar invite and dial-in information.

I look forward to speaking with you all on Tuesday.

Best,
Suzanne

From: Fehrenbacher, Cathy [<mailto:Fehrenbacher.Cathy@epa.gov>]

Sent: Thursday, February 21, 2019 11:15 AM

To: Blair, Susanna <Blair.Susanna@epa.gov>; Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>; Berger, Tom C. <Berger@khlaw.com>

Cc: Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: RE: Coordination Call for GlobalChem Panel

Thanks Suzanne for setting up the coordination call. Tuesday at 1 would also work for me.

Cathy Fehrenbacher, CIH
Acting Director, Risk Assessment Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W. (7403M)
Washington, DC 20460

Phone: (202) 564-8551

Fax: (202) 564-7450

Deliveries: 1201 Constitution Ave N.W., room 6220B EPA East

From: Blair, Susanna

Sent: Thursday, February 21, 2019 11:10 AM

To: 'Hartigan, Suzanne' <Suzanne_Hartigan@americanchemistry.com>; Berger, Tom C. <Berger@khlaw.com>

Cc: Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: RE: Coordination Call for GlobalChem Panel

Ex. 5 Deliberative Process (DP)

Thanks!
Susanna

Susanna W. Blair, PhD

Special Assistant - Office of Pollution Prevention and Toxics

202.564.4371 (office) | 202.322.0538 (cell) | Blair.susanna@epa.gov

From: Hartigan, Suzanne [mailto:Suzanne_Hartigan@americanchemistry.com]

Sent: Thursday, February 21, 2019 10:45 AM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: RE: Coordination Call for GlobalChem Panel

Ex. 5 Deliberative Process (DP)

Thank you,
Suzanne

From: Berger, Tom C. [<mailto:Berger@khlaw.com>]

Sent: Thursday, February 21, 2019 9:06 AM

To: Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>

Cc: Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: RE: Coordination Call for GlobalChem Panel

Does this mean I don't have to pull an all-nighter to finish my slides tonight? :)

From: Risotto, Steve <Steve_Risotto@americanchemistry.com>

Sent: Wednesday, February 20, 2019 9:21 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>; Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>

Subject: Re: Coordination Call for GlobalChem Panel

Suzanne -

The times on Monday and Tuesday work as does 1 pm on Weds.

Steve Risotto

Sent from my iPhone

On Feb 20, 2019, at 3:32 PM, Berger, Tom C. <Berger@khlaw.com> wrote:

I am available all but (1) the 10 AM on Tuesday and (1) the 10 AM on Wednesday. 1:00 slots probably the best for me

From: Hartigan, Suzanne <Suzanne_Hartigan@americanchemistry.com>

Sent: Wednesday, February 20, 2019 3:27 PM

To: Blair, Susanna <Blair.Susanna@epa.gov>; Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>;

Berger, Tom C. <Berger@khlaw.com>; Risotto, Steve <Steve_Risotto@americanchemistry.com>

Subject: Coordination Call for GlobalChem Panel

Dear Susanna, Cathy, Steve, and Tom,

Thank you all for agreeing to participate on our GlobalChem Panel on TSCA prioritization and risk evaluation. You should all have received confirmation letters with more details via email from Susan Blanco at ACC. Please let me know if you didn't receive this yet.

I would like to try to set up a brief 30 min. call to coordinate, if possible. I can suggest a few dates/times (times are in ET) to start, but please let me know if none of these work and I can try some other options.

Monday, February 25 – 10 AM or 1:00 PM

Tuesday, February 26 - 10 AM, 1:00 PM or 4:00 PM

Wednesday, February 27 - 10 AM, 1:00 PM or 4:00 PM

Please let me know your preferences by noon on Friday, February 22nd. If we can find a date/time that works, I will send a calendar invite with dial-in information.

Thanks again,
Suzanne

Suzanne B. Hartigan, Ph.D. | American Chemistry Council
Senior Director, Regulatory and Technical Affairs
suzanne_hartigan@americanchemistry.com
700 2nd Street, NE | Washington, DC | 20002
O: (202) 249-6440
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Asbestos – Not Just a “Legacy” Chemical

March 6, 2019

Thomas C. Berger, Partner

Keller and Heckman LLP
Washington, DC Office
+1 202.434.4285
berger@khlaw.com



Thomas C. "Tom" Berger



Tom Berger is a partner at Keller and Heckman. Tom has a chemical engineering background, and his practice focuses on regulation and approval of new and existing chemicals under the U.S. Toxic Substances Control Act (TSCA) and its international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. Mr. Berger also counsels trade association clients on various matters, including environmental, product disparagement, and product defense issues. Mr. Berger has extensive experience with all aspects of TSCA, including Chemical Data Reporting (CDR) rule issues, TSCA "Work Plan Chemicals," the TSCA Inventory "reset," as well as auditing, liability, enforcement, and EPA "Audit Policy" issues.



Principal sections of TSCA



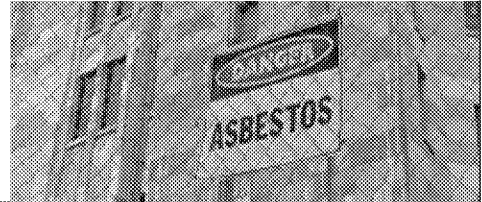
- Section 3 – Definitions
- Section 4 – Test rules/orders
- Section 5 – New Chemicals and Uses
- Section 6 – Unreasonable Risk Regulation
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
- Section 14 – Confidentiality (CBI)
- Sections 15 and 16 – Penalties
- Section 18 – Preemption

Sections of TSCA currently relevant to asbestos



- Section 3 – Definitions
- Section 4 – Test rules/orders
- Section 5 – New Chemicals and Uses
- Section 6 – Unreasonable Risk Regulation
- Section 8 – Recordkeeping and Reporting
- Section 12 – Exports
- Section 13 – Imports
- Section 14 – Confidentiality (CBI)
- Sections 15 and 16 – Prohibited Acts/Penalties
- Section 18 – Preemption

- TSCA §6 rule and partial remand under *Corrosion Proof Fittings* decision (1989-1991)
- Proposed §5 SNUR (2018)
- §21 citizen petition, EPA denial, and more (2018-2019)
- Designation as among first 10 chemicals for §6 risk evaluation (December 2016), publication of “problem formulation” document (May 2018)



Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991)



- On July 12, 1989 EPA issues final §6 rule (“Asbestos Ban and Phase-Out rule”) prohibiting future asbestos activities in almost all products
- Petitioners sued claiming rulemaking procedure flawed and rule not promulgated on basis of substantial evidence
- 5th Circuit remanded rule to EPA for further consideration
 - TSCA requires EPA use “least burdensome regulation” to achieve goal of minimum reasonable risk
 - Because EPA banned all present/future uses of asbestos and complete ban was most burdensome alternative, if any other regulation would achieve acceptable risk then rule cannot stand
 - By not evaluating toxicity of likely substitute products EPA failed to provide basis for benefits of rule
 - EPA, however, allowed to ban future uses in products not yet on the market

Decision was major driver of TSCA reform

Asbestos uses currently banned outright



- Commercial paper
- Corrugated paper
- Flooring felt
- Rollboard
- Specialty paper
- Any use that began/begins after August 25, 1989